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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code section 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

Human Services Department[441]

Replace Chapter 77
Replace Chapter 110

Natural Resource Commission[571]

Replace Analysis
Replace Chapter 40

Public Employment Relations Board[621]

Replace Analysis
Replace Chapter 1
Remove Reserved Chapters 13 to 15
Insert Chapters 13 and 14 and Reserved Chapter 15

Public Health Department[641]

Replace Analysis
Replace Chapters 38 to 41
Replace Chapter 45
Replace Reserved Chapter 154 with Chapter 154

Labor Services Division[875]

Replace Chapter 90

CHAPTER 77
CONDITIONS OF PARTICIPATION FOR PROVIDERS
OF MEDICAL AND REMEDIAL CARE

[Prior to 7/1/83, Social Services[770] Ch 77]

[Prior to 2/11/87, Human Services[498]]

441—77.1(249A) Physicians. All physicians (doctors of medicine and osteopathy) licensed to practice in the state of Iowa are eligible to participate in the program. Physicians in other states are also eligible if duly licensed to practice in that state.

441—77.2(249A) Retail pharmacies. Retail pharmacies are eligible to participate if they meet the requirements of this rule.

77.2(1) *Licensure.* Participating retail pharmacies must be licensed in the state of Iowa or duly licensed in another state. Out-of-state retail pharmacies delivering, dispensing, or distributing drugs by any method to an ultimate user physically located in Iowa must be duly licensed by Iowa as a nonresident pharmacy for that purpose.

77.2(2) *Survey participation.* As a condition of participation, retail pharmacies are required to make available drug acquisition cost invoice information, product availability information if known, dispensing cost information, and any other information deemed necessary by the department to assist in monitoring and revising reimbursement rates pursuant to 441—subrule 79.1(8) or for the efficient operation of the pharmacy benefit.

a. A pharmacy shall produce and submit all requested information in the manner and format requested by the department or its designee at no cost to the department or its designee.

b. A pharmacy shall submit information to the department or its designee within the time frame indicated following receipt of a request for information unless the department or its designee grants an extension upon written request of the pharmacy.

c. Any dispensing or acquisition cost information submitted to the department that specifically identifies a pharmacy's individual costs shall be held confidential.

[ARC 0485C, IAB 12/12/12, effective 2/1/13]

441—77.3(249A) Hospitals.

77.3(1) *Qualifications.* All hospitals licensed in the state of Iowa or in another state and certified as eligible to participate in Part A of the Medicare program (Title XVIII of the Social Security Act) are eligible to participate in the medical assistance program, subject to the additional requirements of this rule.

77.3(2) *Referral to health home services provider.* As a condition of participation in the medical assistance program, hospitals must establish procedures for referring to health home services providers any members who seek or need treatment in the hospital emergency department and who are eligible for health home services pursuant to 441—subrule 78.53(2).

This rule is intended to implement Iowa Code section 249A.4.

[ARC 0198C, IAB 7/11/12, effective 7/1/12]

441—77.4(249A) Dentists. All dentists licensed to practice in the state of Iowa are eligible to participate in the program. Dentists in other states are also eligible if duly licensed to practice in that state.

NOTE: DENTAL LABORATORIES—Payment will not be made to a dental laboratory.

441—77.5(249A) Podiatrists. All podiatrists licensed to practice in the state of Iowa are eligible to participate in the program. Podiatrists in other states are also eligible if duly licensed to practice in that state.

441—77.6(249A) Optometrists. All optometrists licensed to practice in the state of Iowa are eligible to participate in the program. Optometrists in other states are also eligible if duly licensed to practice in that state.

441—77.7(249A) Opticians. All opticians in the state of Iowa are eligible to participate in the program. Opticians in other states are also eligible to participate.

NOTE: Opticians in states having licensing requirements for this professional group must be duly licensed in that state.

441—77.8(249A) Chiropractors. All chiropractors licensed to practice in the state of Iowa are eligible to participate providing they have been determined eligible to participate in Title XVIII of the Social Security Act (Medicare) by the Social Security Administration. Chiropractors in other states are also eligible if duly licensed to practice in that state and determined eligible to participate in Title XVIII of the Social Security Act.

441—77.9(249A) Home health agencies. Home health agencies are eligible to participate providing they are certified to participate in the Medicare program (Title XVIII of the Social Security Act) and, unless exempted under subrule 77.9(5), have submitted a surety bond as required by subrules 77.9(1) to 77.9(6).

77.9(1) Definitions.

“Assets” includes any listing that identifies Medicaid members to whom home health services were furnished by a participating or formerly participating home health agency.

“Rider” means a notice issued by a surety that a change in the bond has occurred or will occur.

“Uncollected overpayment” means a Medicaid overpayment, including accrued interest, for which the home health agency is responsible that has not been recouped by the department within 60 days from the date of notification that an overpayment has been identified.

77.9(2) Parties to surety bonds. The surety bond shall name the home health agency as the principal, the Iowa department of human services as the obligee and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as surety. The bond shall be issued by a company holding a current Certificate of Authority issued by the U.S. Department of the Treasury in accordance with 31 U.S.C. Sections 9304 to 9308 and 31 CFR Part 223 as amended to November 30, 1984, Part 224 as amended to May 29, 1996, and Part 225 as amended to September 12, 1974. The bond shall list the surety’s name, street address or post office box number, city, state and ZIP code. The company shall not have been determined by the department to be unauthorized in Iowa due to:

a. Failure to furnish timely confirmation of the issuance of and the validity and accuracy of information appearing on a surety bond that a home health agency presents to the department that shows the surety company as surety on the bond.

b. Failure to timely pay the department in full the amount requested, up to the face amount of the bond, upon presentation by the department to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company’s liability on the bond.

c. Other good cause.

The department shall give public notice of a determination that a surety company is unauthorized in Iowa and the effective date of the determination by publication of a notice in the newspaper of widest circulation in each city in Iowa with a population of 50,000 or more. A list of surety companies determined by the department to be unauthorized in Iowa shall be maintained and shall be available for public inspection by contacting the division of medical services of the department. The determination that a surety company is unauthorized in Iowa has effect only in Iowa and is not a debarment, suspension, or exclusion for the purposes of Federal Executive Order No. 12549.

77.9(3) Surety company obligations. The bond shall guarantee payment to the department, up to the face amount of the bond, of the full amount of any uncollected overpayment, including accrued interest, based on payments made to the home health agency during the term of the bond. The bond shall provide that payment may be demanded from the surety after available administrative collection methods for collecting from the home health agency have been exhausted.

77.9(4) Surety bond requirements. Surety bonds secured by home health agencies participating in Medicaid shall comply with the following requirements:

a. *Effective dates and submission dates.*

(1) Home health agencies participating in the program on June 10, 1998, shall secure either an initial surety bond for the period January 1, 1998, through the end of the home health agency's fiscal year or a continuous bond which remains in effect from year to year.

(2) Home health agencies seeking to participate in Medicaid and Medicare for the first time after June 10, 1998, shall secure an initial surety bond for the period from Medicaid certification through the end of the home health agency's fiscal year or a continuous bond which remains in effect from year to year.

(3) Medicare-certified home health agencies seeking to participate in Medicaid for the first time after June 10, 1998, shall secure an initial surety bond for the period from Medicaid certification through the end of the home health agency's fiscal year or a continuous bond which remains in effect from year to year.

(4) Home health agencies seeking to participate in Medicaid after purchasing the assets of or an ownership interest in a participating or formerly participating agency shall secure an initial surety bond effective as of the date of purchase of the assets or the transfer of the ownership interest for the balance of the current fiscal year of the home health agency or a continuous bond which remains in effect from year to year.

(5) Home health agencies which continue to participate in Medicaid after the period covered by an initial surety bond shall secure a surety bond for each subsequent fiscal year of the home health agency or a continuous bond which remains in effect from year to year.

b. Amount of bond. Bonds for any period shall be in the amount of \$50,000 or 15 percent of the home health agency's annual Medicaid payments during the most recently completed state fiscal year, whichever is greater. After June 1, 2005, all bonds shall be in the amount of \$50,000. At least 90 days before the start of each home health agency's fiscal year, the department shall provide notice of the amount of the surety bond to be purchased and submitted to the Iowa Medicaid enterprise provider services unit.

c. Other requirements. Surety bonds shall meet the following additional requirements. The bond shall:

(1) Guarantee that upon written demand by the department to the surety for payment under the bond and the department's furnishing to the surety sufficient evidence to establish the surety's liability under the bond, the surety shall within 60 days pay the department the amount so demanded, up to the stated amount of the bond.

(2) Provide that the surety's liability for uncollected overpayments is based on overpayments determined during the term of the bond.

(3) Provide that the surety's liability to the department is not extinguished by any of the following:

1. Any action by the home health agency or the surety to terminate or limit the scope or term of the bond unless the surety furnishes the department with notice of the action not later than 10 days after the date of notice of the action by the home health agency to the surety and not later than 60 days before the effective date of the action by the surety.

2. The surety's failure to continue to meet the requirements in subrule 77.9(2) or the department's determination that the surety company is an unauthorized surety under subrule 77.9(2).

3. Termination of the home health agency's provider agreement.

4. Any action by the department to suspend, offset, or otherwise recover payments to the home health agency.

5. Any action by the home health agency to cease operations, sell or transfer any assets or ownership interest, file for bankruptcy, or fail to pay the surety.

6. Any fraud, misrepresentation, or negligence by the home health agency in obtaining the surety bond or by the surety (or the surety's agent, if any) in issuing the surety bond; except that any fraud, misrepresentation, or negligence by the home health agency in identifying to the surety (or the surety's agent) the amount of Medicaid payments upon which the amount of the surety bond is determined shall not cause the surety's liability to the department to exceed the amount of the bond.

7. The home health agency's failure to exercise available appeal rights under Medicaid or assign appeal rights to the surety.

(4) Provide that if a home health agency fails to furnish a bond following the expiration date of an annual bond or if a home health agency fails to furnish a rider for a year in which a rider is required or if the home health agency's provider agreement with the department is terminated, the surety shall remain liable under the most recent annual bond or rider to a continuous bond for two years from the date the home health agency was required to submit the annual bond or rider to a continuous bond or for two years from the termination date of the provider agreement.

(5) Provide that actions under the bond may be brought by the department or by an agent designated by the department.

(6) Provide that the surety may appeal department decisions.

77.9(5) *Exemption from surety bond requirements for government-operated home health agencies.* A home health agency operated by a federal, state, local, or tribal government agency is exempt from the bonding requirements of this rule if, during the preceding five years, the home health agency has not had any uncollected overpayments. Government-operated home health agencies having uncollected overpayments during the preceding five years shall not be exempted from the bonding requirements of this rule.

77.9(6) *Government-operated home health agency that loses its exemption.* A government-operated home health agency which has met the criteria for an exemption under subrule 77.9(6) but is later determined by the department not to meet the criteria shall submit a surety bond within 60 days of the date of the department's written notification to the home health agency that it no longer meets the criteria for an exemption, for the period and in the amount required in the notice from the department.

441—77.10(249A) Medical equipment and appliances, prosthetic devices and medical supplies. All dealers in medical equipment and appliances, prosthetic devices and medical supplies in Iowa or in other states are eligible to participate in the program.

441—77.11(249A) Ambulance service. Providers of ambulance service are eligible to participate providing they meet the eligibility requirements for participation in the Medicare program (Title XVIII of the Social Security Act).

441—77.12(249A) Behavioral health intervention. A provider of behavioral health intervention is eligible to participate in the medical assistance program when the provider is enrolled in the Iowa Plan for Behavioral Health pursuant to 441—Chapter 88, Division IV. Providers must complete child abuse, dependent adult abuse, and criminal background screenings pursuant to Iowa Code section 135C.33(5)“a”(1) before employment of a staff member who will provide direct care.

This rule is intended to implement Iowa Code section 249A.4 and 2010 Iowa Acts, chapter 1192, section 31.

[ARC 7741B, IAB 5/6/09, effective 7/1/09; ARC 9487B, IAB 5/4/11, effective 7/1/11]

441—77.13(249A) Hearing aid dispensers. Hearing aid dispensers are eligible to participate if they are duly licensed by the state of Iowa. Hearing aid dispensers in other states will be eligible to participate if they are duly licensed in that state.

This rule is intended to implement Iowa Code section 249A.4.

441—77.14(249A) Audiologists. Audiologists are eligible to participate in the program when they are duly licensed by the state of Iowa. Audiologists in other states will be eligible to participate when they are duly licensed in that state. In states having no licensure requirement for audiologists, an audiologist shall obtain a license from the state of Iowa.

This rule is intended to implement Iowa Code section 249A.4.

441—77.15(249A) Community mental health centers. Community mental health centers are eligible to participate in the medical assistance program when they comply with the standards for mental health centers in the state of Iowa established by the Iowa mental health authority.

This rule is intended to implement Iowa Code section 249A.4.

441—77.16(249A) Screening centers. Public or private health agencies are eligible to participate as screening centers when they have the staff and facilities needed to perform all of the elements of screening specified in 441—78.18(249A) and meet the department of public health's standards for a child health screening center. The staff members must be employed by or under contract with the screening center. Screening centers shall direct applications to participate to the Iowa Medicaid enterprise provider services unit.

This rule is intended to implement Iowa Code section 249A.4.

441—77.17(249A) Physical therapists. Physical therapists are eligible to participate when they are licensed, in independent practice; and are eligible to participate in the Medicare program.

This rule is intended to implement Iowa Code section 249A.4.

441—77.18(249A) Orthopedic shoe dealers and repair shops. Establishments eligible to participate in the medical assistance program are retail dealers in orthopedic shoes prescribed by physicians or podiatrists and shoe repair shops specializing in orthopedic work as prescribed by physicians or podiatrists.

This rule is intended to implement Iowa Code section 249A.4.

441—77.19(249A) Rehabilitation agencies. Rehabilitation agencies are eligible to participate providing they are certified to participate in the Medicare program (Title XVIII of the Social Security Act).

This rule is intended to implement Iowa Code section 249A.4.

441—77.20(249A) Independent laboratories. Independent laboratories are eligible to participate providing they are certified to participate as a laboratory in the Medicare program (Title XVIII of the Social Security Act). An independent laboratory is a laboratory that is independent of attending and consulting physicians' offices, hospitals, and critical access hospitals.

This rule is intended to implement Iowa Code section 249A.4.

441—77.21(249A) Rural health clinics. Rural health clinics are eligible to participate providing they are certified to participate in the Medicare program (Title XVIII of the Social Security Act).

441—77.22(249A) Psychologists. All psychologists licensed to practice in the state of Iowa and meeting the standards of the National Register of Health Service Providers in Psychology, 1981 edition, published by the council for the National Register of Health Service Providers in Psychology, are eligible to participate in the medical assistance program. Psychologists in other states are eligible to participate when they are duly licensed to practice in that state and meet the standards of the National Register of Health Service Providers in Psychology.

This rule is intended to implement Iowa Code sections 249A.4 and 249A.15.

441—77.23(249A) Maternal health centers. A maternal health center is eligible to participate in the Medicaid program if the center provides a team of professionals to render prenatal and postpartum care and enhanced perinatal services (see rule 441—78.25(249A)). The prenatal and postpartum care shall be in accordance with the latest edition of the American College of Obstetricians and Gynecologists, Standards for Obstetric Gynecologic Services. The team must have at least a physician, a registered nurse, a licensed dietitian and a person with at least a bachelor's degree in social work, counseling, sociology or psychology. Team members must be employed by or under contract with the center.

This rule is intended to implement Iowa Code section 249A.4.

441—77.24(249A) Ambulatory surgical centers. Ambulatory surgical centers that are not part of hospitals are eligible to participate in the medical assistance program if they are certified to participate in the Medicare program (Title XVIII of the Social Security Act). Freestanding ambulatory surgical centers providing only dental services are also eligible to participate in the medical assistance program

if the board of dental examiners has issued a current permit pursuant to 650—Chapter 29 for any dentist to administer deep sedation or general anesthesia at the facility.

441—77.25(249A) Home- and community-based habilitation services. To be eligible to participate in the Medicaid program as an approved provider of home- and community-based habilitation services, a provider shall be an enrolled provider of habilitation with the Iowa Plan for Behavioral Health and meet the general requirements in subrules 77.25(2), 77.25(3), and 77.25(4) and shall meet the requirements in the subrules applicable to the individual services being provided.

77.25(1) Definitions.

“Guardian” means a guardian appointed in probate or juvenile court.

“Major incident” means an occurrence involving a member during service provision that:

1. Results in a physical injury to or by the member that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the member;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a member’s location being unknown by provider staff who are assigned protective oversight.

“Member” means a person who has been determined to be eligible for Medicaid under 441—Chapter 75.

“Minor incident” means an occurrence involving a member during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

77.25(2) Organization and staff.

a. The prospective provider shall demonstrate the fiscal capacity to initiate and operate the specified programs on an ongoing basis.

b. The provider shall complete child abuse, dependent adult abuse, and criminal background screenings pursuant to Iowa Code section 249A.29 before employing a person who will provide direct care.

c. A person providing direct care shall be at least 16 years of age.

d. A person providing direct care shall not be an immediate family member of the member.

77.25(3) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS habilitation service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule.

a. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the member’s file.

b. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member's supervisor.
2. The member or the member's legal guardian. EXCEPTION: Notification to the member is required only if the incident took place outside of the provider's service provision. Notification to the guardian, if any, is always required.

3. The member's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the member involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other members or nonmembers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the member's file.

c. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of members served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

77.25(4) Restraint, restriction, and behavioral intervention. The provider shall have in place a system for the review, approval, and implementation of ethical, safe, humane, and efficient behavioral intervention procedures. All members receiving home- and community-based habilitation services shall be afforded the protections imposed by these rules when any restraint, restriction, or behavioral intervention is implemented.

a. The system shall include procedures to inform the member and the member's legal guardian of the restraint, restriction, and behavioral intervention policy and procedures at the time of service approval and as changes occur.

b. Restraint, restriction, and behavioral intervention shall be used only for reducing or eliminating maladaptive target behaviors that are identified in the member's restraint, restriction, or behavioral intervention program.

c. Restraint, restriction, and behavioral intervention procedures shall be designed and implemented only for the benefit of the member and shall never be used as punishment, for the convenience of the staff, or as a substitute for a nonaversive program.

d. Restraint, restriction, and behavioral intervention programs shall be time-limited and shall be reviewed at least quarterly.

e. Corporal punishment and verbal or physical abuse are prohibited.

77.25(5) Case management. The department of human services, a county or consortium of counties, or a provider under subcontract to the department or to a county or consortium of counties is eligible to participate in the home- and community-based habilitation services program as a provider of case management services provided that the agency meets the standards in 441—Chapter 24.

77.25(6) Day habilitation. The following providers may provide day habilitation:

a. An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities to provide services that qualify as day habilitation under 441—subrule 78.27(8).

b. An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities to provide other services and began providing services that qualify as day habilitation under 441—subrule 78.27(8) since the agency's last accreditation survey. The agency may provide day habilitation services until the current accreditation expires. When the current accreditation expires, the agency must qualify under paragraph "*a*," "*d*," "*g*," or "*h*."

c. An agency that is not accredited by the Commission on Accreditation of Rehabilitation Facilities but has applied to the Commission within the last 12 months for accreditation to provide services that qualify as day habilitation under 441—subrule 78.27(8). An agency that has not received accreditation within 12 months after application to the Commission is no longer a qualified provider.

d. An agency that is accredited by the Council on Quality and Leadership in Supports for People with Disabilities.

e. An agency that has applied to the Council on Quality and Leadership in Supports for People with Disabilities for accreditation within the last 12 months. An agency that has not received accreditation within 12 months after application to the Council is no longer a qualified provider.

f. An agency that is accredited under 441—Chapter 24 to provide day treatment or supported community living services.

g. An agency that is certified by the department to provide day habilitation services under the home- and community-based services intellectual disability waiver pursuant to rule 441—77.37(249A).

h. An agency that is accredited by the International Center for Clubhouse Development.

i. An agency that is accredited by the Joint Commission on Accreditation of Healthcare Organizations.

j. A residential care facility of more than 16 beds that is licensed by the Iowa department of inspections and appeals, was enrolled as a provider of rehabilitation services for adults with chronic mental illness before December 31, 2006, and has applied for accreditation through one of the accrediting bodies listed in this subrule.

(1) The facility must have policies in place by June 30, 2007, consistent with the accreditation being sought.

(2) A facility that has not received accreditation within 12 months after application for accreditation is no longer a qualified provider.

77.25(7) *Home-based habilitation.* The following agencies may provide home-based habilitation services:

a. An agency that is certified by the department to provide supported community living services under:

(1) The home- and community-based services intellectual disability waiver pursuant to rule 441—77.37(249A); or

(2) The home- and community-based services brain injury waiver pursuant to rule 441—77.39(249A).

b. An agency that is accredited under 441—Chapter 24 to provide supported community living services.

c. An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities as a community housing or supported living service provider.

d. An agency that is accredited by the Council on Quality and Leadership in Supports for People with Disabilities.

e. An agency that is accredited by the Council on Accreditation of Services for Families and Children.

f. An agency that is accredited by the Joint Commission on Accreditation of Healthcare Organizations.

g. A residential care facility of 16 or fewer beds that is licensed by the Iowa department of inspections and appeals, was enrolled as a provider of rehabilitation services for adults with chronic

mental illness before December 31, 2006, and has applied for accreditation through one of the accrediting bodies listed in this subrule.

(1) The facility must have policies in place by June 30, 2007, consistent with the accreditation being sought.

(2) A facility that has not received accreditation within 12 months after application for accreditation is no longer a qualified provider.

77.25(8) *Prevocational habilitation.* The following providers may provide prevocational services:

a. An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities as an organizational employment service provider or a community employment service provider.

b. An agency that is accredited by the Council on Quality and Leadership in Supports for People with Disabilities.

c. An agency that is accredited by the International Center for Clubhouse Development.

d. An agency that is certified by the department to provide prevocational services under:

(1) The home- and community-based services intellectual disability waiver pursuant to rule 441—77.37(249A); or

(2) The home- and community-based services brain injury waiver pursuant to rule 441—77.39(249A).

77.25(9) *Supported employment habilitation.* The following agencies may provide supported employment services:

a. An agency that is certified by the department to provide supported employment services under:

(1) The home- and community-based services intellectual disability waiver pursuant to rule 441—77.37(249A); or

(2) The home- and community-based services brain injury waiver pursuant to rule 441—77.39(249A).

b. An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities as an organizational employment service provider or a community employment service provider.

c. An agency that is accredited by the Council on Accreditation of Services for Families and Children.

d. An agency that is accredited by the Joint Commission on Accreditation of Healthcare Organizations.

e. An agency that is accredited by the Council on Quality and Leadership in Supports for People with Disabilities.

f. An agency that is accredited by the International Center for Clubhouse Development.

77.25(10) *Provider enrollment.* A prospective provider that meets the criteria in this rule and the provider criteria of the Iowa Plan for Behavioral Health contractor must be enrolled through the Iowa Plan for Behavioral Health contractor as an approved provider of a specific component of home- and community-based habilitation services. Enrollment carries no assurance that the approved provider will receive funding. The Iowa Medicaid enterprise will enroll providers with Medicaid only when the provider is enrolled in the Iowa Plan for Behavioral Health. Payment for services will be made to a provider only when the provider is enrolled in the Iowa Plan for Behavioral Health and the provider is authorized to provide the services. This includes payments made by the Iowa Medicaid enterprise for services provided to members who are not eligible to enroll in the Iowa Plan for Behavioral Health.

a. The Iowa Plan for Behavioral Health contractor shall review compliance with standards for initial enrollment. Review of a provider may occur at any time.

b. The department or the Iowa Plan for Behavioral Health contractor may request any information from the prospective service provider that is pertinent to arriving at an enrollment decision. This information may include:

(1) Current accreditations.

(2) Evaluations.

(3) Inspection reports.

(4) Reviews by regulatory and licensing agencies and associations.

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 0848C, IAB 7/24/13, effective 7/1/13; ARC 1051C, IAB 10/2/13, effective 11/6/13]

441—77.26(249A) Behavioral health services. The following persons are eligible to participate in the Medicaid program as providers of behavioral health services.

77.26(1) Licensed marital and family therapists (LMFT). Any person licensed by the board of behavioral science as a marital and family therapist pursuant to 645—Chapter 31 is eligible to participate. A marital and family therapist in another state is eligible to participate when duly licensed to practice in that state.

77.26(2) Licensed independent social workers (LISW). Any person licensed by the board of social work as an independent social worker pursuant to 645—Chapter 280 is eligible to participate. An independent social worker in another state is eligible to participate when duly licensed to practice in that state.

77.26(3) Licensed master social workers (LMSW).

a. A person licensed by the board of social work as a master social worker pursuant to 645—Chapter 280 is eligible to participate when the person:

- (1) Holds a master's or doctoral degree as approved by the board of social work; and
- (2) Provides treatment under the supervision of an independent social worker licensed pursuant to 645—Chapter 280.

b. A master social worker in another state is eligible to participate when the person:

- (1) Is duly licensed to practice in that state; and
- (2) Provides treatment under the supervision of an independent social worker duly licensed in that state.

77.26(4) Licensed mental health counselors (LMC). Any person licensed by the board of behavioral science as a mental health counselor pursuant to Iowa Code chapter 154D and 645—Chapter 31 is eligible to participate. A mental health counselor in another state is eligible to participate when duly licensed to practice in that state.

77.26(5) Certified alcohol and drug counselors. Any person certified by the nongovernmental Iowa board of substance abuse certification as an alcohol and drug counselor is eligible to participate.

This rule is intended to implement Iowa Code chapter 249A as amended by 2011 Iowa Acts, Senate File 233.

[ARC 9649B, IAB 8/10/11, effective 8/1/11]

441—77.27(249A) Birth centers. Birth centers are eligible to participate in the Medicaid program if they are licensed or receive reimbursement from at least two third-party payors.

This rule is intended to implement Iowa Code section 249A.4.

441—77.28(249A) Area education agencies. An area education agency is eligible to participate in the Medicaid program when it has a plan for providing comprehensive special education programs and services approved by the Iowa department of education. Covered services shall be provided by personnel who are licensed, endorsed, or registered as provided in this rule and shall be within the scope of the applicable license, endorsement, or registration.

77.28(1) Personnel providing audiological or speech-language services shall be licensed by the Iowa board of speech pathology and audiology as a speech pathologist or audiologist pursuant to 645—Chapters 299, 300 and 303 through 305.

77.28(2) Personnel providing physical therapy shall be licensed by the Iowa board of physical and occupational therapy as a physical therapist pursuant to 645—Chapters 199 through 204.

77.28(3) Personnel providing occupational therapy shall be licensed by the Iowa board of physical and occupational therapy as an occupational therapist pursuant to 645—Chapters 205 through 210.

77.28(4) Personnel providing psychological evaluations and counseling or psychotherapy services shall be:

- a.* Endorsed by the Iowa board of educational examiners as a school psychologist pursuant to rule 282—15.11(272);
- b.* Licensed by the Iowa board of psychology as a psychologist pursuant to 645—Chapters 239 through 243;
- c.* Licensed by the Iowa board of social work as a social worker pursuant to 645—Chapters 279 through 284;
- d.* Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11; or
- e.* Registered by the Iowa nursing board as an advanced registered nurse practitioner pursuant to 655—Chapter 7.

77.28(5) Personnel providing nursing services shall be licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6.

77.28(6) Personnel providing vision services shall be:

- a.* Licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6;
 - b.* Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11; or
 - c.* Licensed by the Iowa board of optometry as an optometrist pursuant to 645—Chapter 180.
- This rule is intended to implement Iowa Code section 249A.4.

441—77.29(249A) Case management provider organizations. Case management provider organizations are eligible to participate in the Medicaid program provided that they meet the standards for the populations being served. Providers shall meet the following standards:

77.29(1) Standards in 441—Chapter 24. Providers shall meet the standards in 441—Chapter 24 when they are the department of human services, a county or consortium of counties, or an agency or provider under subcontract to the department or a county or consortium of counties providing case management services to persons with mental retardation, developmental disabilities or chronic mental illness.

77.29(2) Standards in 441—Chapter 186. Rescinded IAB 10/12/05, effective 10/1/05.

441—77.30(249A) HCBS health and disability waiver service providers. HCBS health and disability waiver services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the member served or the parent or stepparent of a member aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A provider hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider. The following providers shall be eligible to participate in the Medicaid HCBS health and disability waiver program if they meet the standards in subrule 77.30(18) and also meet the standards set forth below for the service to be provided:

77.30(1) Homemaker providers. Homemaker providers shall be agencies that are:

- a.* Certified as a home health agency under Medicare, or
- b.* Authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

77.30(2) Home health aide providers. Home health aide providers shall be agencies which are certified to participate in the Medicare program.

77.30(3) Adult day care providers. Adult day care providers shall be agencies that are certified by the department of inspections and appeals as being in compliance with the standards for adult day services programs at 481—Chapter 70.

77.30(4) Nursing care providers. Nursing care providers shall be agencies which are certified to participate in the Medicare program as home health agencies.

77.30(5) Respite care providers.

a. The following agencies may provide respite services:

- (1) Home health agencies that are certified to participate in the Medicare program.
- (2) Respite providers certified under the home- and community-based services intellectual disability or brain injury waiver.
- (3) Nursing facilities, intermediate care facilities for the mentally retarded, and hospitals enrolled as providers in the Iowa Medicaid program.
- (4) Group living foster care facilities for children licensed by the department according to 441—Chapters 112 and 114 to 116 and child care centers licensed according to 441—Chapter 109.
- (5) Camps certified by the American Camping Association.
- (6) Home care agencies that meet the conditions of participation set forth in subrule 77.30(1).
- (7) Adult day care providers that meet the conditions of participation set forth in subrule 77.30(3).
- (8) Residential care facilities for persons with mental retardation licensed by the department of inspections and appeals.

(9) Assisted living programs certified by the department of inspections and appeals.

b. Respite providers shall meet the following conditions:

- (1) Providers shall maintain the following information that shall be updated at least annually:
 1. The consumer's name, birth date, age, and address and the telephone number of each parent, guardian or primary caregiver.
 2. An emergency medical care release.
 3. Emergency contact telephone numbers such as the number of the consumer's physician and the parents, guardian, or primary caregiver.
 4. The consumer's medical issues, including allergies.
 5. The consumer's daily schedule which includes the consumer's preferences in activities or foods or any other special concerns.

(2) Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered. Home health agencies must follow Medicare regulations for medication dispensing.

All medications shall be stored in their original containers, with the accompanying physician's or pharmacist's directions and label intact. Medications shall be stored so they are inaccessible to consumers and the public. Nonprescription medications shall be labeled with the consumer's name.

In the case of medications that are administered on an ongoing, long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription.

(3) Policies shall be developed for:

1. Notifying the parent, guardian or primary caregiver of any injuries or illnesses that occur during respite provision. A parent's, guardian's or primary caregiver's signature is required to verify receipt of notification.
2. Requiring the parent, guardian or primary caregiver to notify the respite provider of any injuries or illnesses that occurred prior to respite provision.
3. Documenting activities and times of respite. This documentation shall be made available to the parent, guardian or primary caregiver upon request.
4. Ensuring the safety and privacy of the individual. Policies shall at a minimum address threat of fire, tornado, or flood and bomb threats.

c. A facility providing respite under this subrule shall not exceed the facility's licensed capacity, and services shall be provided in locations consistent with licensure.

d. Respite provided outside the consumer's home or the facility covered by the licensure, certification, accreditation, or contract must be approved by the parent, guardian or primary caregiver and the interdisciplinary team and must be consistent with the way the location is used by the general public. Respite in these locations shall not exceed 72 continuous hours.

77.30(6) Counseling providers. Counseling providers shall be:

a. Agencies which are certified under the community mental health center standards established by the mental health and developmental disabilities commission, set forth in 441—Chapter 24, Divisions I and III.

b. Agencies which are licensed as meeting the hospice standards and requirements set forth in department of inspections and appeals rules 481—Chapter 53 or which are certified to meet the standards under the Medicare program for hospice programs.

c. Agencies which are accredited under the mental health service provider standards established by the mental health and developmental disabilities commission, set forth in 441—Chapter 24, Divisions I and IV.

77.30(7) *Consumer-directed attendant care providers.* The following providers may provide consumer-directed attendant care service:

- a.* An individual who contracts with the member to provide attendant care service and who is:
- (1) At least 18 years of age.
 - (2) Qualified by training or experience to carry out the member's plan of care pursuant to the department-approved case plan or individual comprehensive plan.
 - (3) Not the spouse of the member or a parent or stepparent of a member aged 17 or under.
 - (4) Not the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

b. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

c. Home health agencies which are certified to participate in the Medicare program.

d. Chore providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating that the organization is qualified to provide chore services.

e. Community action agencies as designated in Iowa Code section 216A.93.

f. Providers certified under an HCBS waiver for supported community living.

g. Assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.

h. Adult day service providers that are certified by the department of inspections and appeals under 481—Chapter 70.

77.30(8) *Interim medical monitoring and treatment providers.*

a. The following providers may provide interim medical monitoring and treatment services:

- (1) Home health agencies certified to participate in the Medicare program.
- (2) Supported community living providers certified according to subrule 77.37(14) or 77.39(13).

b. Staff requirements. Staff members providing interim medical monitoring and treatment services to members shall meet all of the following requirements:

- (1) Be at least 18 years of age.
- (2) Not be the spouse of the member or a parent or stepparent of the member if the member is aged 17 or under.
- (3) Not be a usual caregiver of the member.
- (4) Be qualified by training or experience to provide medical intervention or intervention in a medical emergency necessary to carry out the member's plan of care. The training or experience required must be determined by the member's usual caregivers and a licensed medical professional on the member's interdisciplinary team and must be documented in the member's service plan.

c. Service documentation. Providers shall maintain clinical and fiscal records necessary to fully disclose the extent of services furnished to members. Records shall specify by service date the procedures performed, together with information concerning progress of treatment.

77.30(9) *Home and vehicle modification providers.* The following providers may provide home and vehicle modification:

- a.* Area agencies on aging as designated in 17—4.4(231).
- b.* Community action agencies as designated in Iowa Code section 216A.93.

c. Providers eligible to participate as home and vehicle modification providers under the elderly waiver, enrolled as home and vehicle modification providers under the physical disability waiver, or certified as home and vehicle modification providers under the home- and community-based services intellectual disability or brain injury waiver.

d. Community businesses that have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations, and that submit verification of current liability and workers' compensation coverage.

77.30(10) *Personal emergency response system providers.* Personal emergency response system providers shall be agencies that meet the conditions of participation set forth in subrule 77.33(2).

77.30(11) *Home-delivered meals.* The following providers may provide home-delivered meals:

a. Area agencies on aging as designated in 17—4.4(231). Home-delivered meals providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating the organization is qualified to provide home-delivered meals services may also provide home-delivered meals services.

b. Community action agencies as designated in Iowa Code section 216A.93.

c. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

d. Restaurants licensed and inspected under Iowa Code chapter 137F.

e. Hospitals enrolled as Medicaid providers.

f. Home health aide providers meeting the standards set forth in subrule 77.33(3).

g. Medical equipment and supply dealers certified to participate in the Medicaid program.

h. Home care providers meeting the standards set forth in subrule 77.33(4).

77.30(12) *Nutritional counseling.* The following providers may provide nutritional counseling by a dietitian licensed under 645—Chapter 81:

a. Hospitals enrolled as Medicaid providers.

b. Community action agencies as designated in Iowa Code section 216A.93.

c. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

d. Home health agencies certified by Medicare.

e. Independent licensed dietitians approved by an area agency on aging.

77.30(13) *Financial management service.* Members who elect the consumer choices option shall work with a financial institution that meets the following qualifications.

a. The financial institution shall either:

(1) Be cooperative, nonprofit, member-owned and member-controlled, and federally insured through and chartered by either the National Credit Union Administration (NCUA) or the credit union division of the Iowa department of commerce; or

(2) Be chartered by the Office of the Comptroller of the Currency, a bureau of the U.S. Department of the Treasury, and insured by the Federal Deposit Insurance Corporation (FDIC).

b. The financial institution shall complete a financial management readiness review and certification conducted by the department or its designee.

c. The financial institution shall obtain an Internal Revenue Service federal employee identification number dedicated to the financial management service.

d. The financial institution shall enroll as a Medicaid provider.

77.30(14) *Independent support brokerage.* Members who elect the consumer choices option shall work with an independent support broker who meets the following qualifications.

a. The broker must be at least 18 years of age.

b. The broker shall not be the member's guardian, conservator, attorney in fact under a durable power of attorney for health care, power of attorney for financial matters, trustee, or representative payee.

c. The broker shall not provide any other paid service to the member.

d. The broker shall not work for an individual or entity that is providing services to the member.

e. The broker must consent to a criminal background check and child and dependent adult abuse checks. The results shall be provided to the member.

f. The broker must complete independent support brokerage training approved by the department.

77.30(15) *Self-directed personal care.* Members who elect the consumer choices option may choose to purchase self-directed personal care services from an individual or business that meets the following requirements.

- a.* A business providing self-directed personal care services shall:
 - (1) Have all the necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations; and
 - (2) Have current liability and workers' compensation coverage.
- b.* An individual providing self-directed personal care services shall have all the necessary licenses required by federal, state, and local laws, including a valid driver's license if providing transportation.
- c.* All personnel providing self-directed personal care services shall:
 - (1) Be at least 16 years of age.
 - (2) Be able to communicate successfully with the member.
 - (3) Not be the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.
 - (4) Not be the recipient of respite services paid through the consumer choices option on behalf of a member who receives the consumer choices option.
 - (5) Not be the parent or stepparent of a minor child member or the spouse of a member.
- d.* The provider of self-directed personal care services shall:
 - (1) Prepare timecards or invoices approved by the department that identify what services were provided and the time when services were provided.
 - (2) Submit invoices and timesheets to the financial management service no later than 30 calendar days from the date when the last service in the billing period was provided. Payment shall not be made if invoices and timesheets are received after this 30-day period.

77.30(16) *Individual-directed goods and services.* Members who elect the consumer choices option may choose to purchase individual-directed goods and services from an individual or business that meets the following requirements.

- a.* A business providing individual-directed goods and services shall:
 - (1) Have all the necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations; and
 - (2) Have current liability and workers' compensation coverage.
- b.* An individual providing individual-directed goods and services shall have all the necessary licenses required by federal, state, and local laws, including a valid driver's license if providing transportation.
- c.* All personnel providing individual-directed goods and services shall:
 - (1) Be at least 18 years of age.
 - (2) Be able to communicate successfully with the member.
 - (3) Not be the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.
 - (4) Not be the recipient of respite services paid through the consumer choices option on behalf of a member who receives the consumer choices option.
 - (5) Not be the parent or stepparent of a minor child member or the spouse of a member.
- d.* The provider of individual-directed goods and services shall:
 - (1) Prepare timecards or invoices approved by the department that identify what services were provided and the time when services were provided.
 - (2) Submit invoices and timesheets to the financial management service no later than 30 calendar days from the date when the last service in the billing period was provided. Payment shall not be made if invoices and timesheets are received after this 30-day period.

77.30(17) *Self-directed community supports and employment.* Members who elect the consumer choices option may choose to purchase self-directed community supports and employment from an individual or business that meets the following requirements.

- a.* A business providing community supports and employment shall:

(1) Have all the necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations; and

(2) Have current liability and workers' compensation coverage.

b. An individual providing self-directed community supports and employment shall have all the necessary licenses required by federal, state, and local laws, including a valid driver's license if providing transportation.

c. All personnel providing self-directed community supports and employment shall:

(1) Be at least 18 years of age.

(2) Be able to communicate successfully with the member.

(3) Not be the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

(4) Not be the recipient of respite services paid through the consumer choices option on behalf of a member who receives the consumer choices option.

(5) Not be the parent or stepparent of a minor child member or the spouse of a member.

d. The provider of self-directed community supports and employment shall:

(1) Prepare timecards or invoices approved by the department that identify what services were provided and the time when services were provided.

(2) Submit invoices and timesheets to the financial management service no later than 30 calendar days from the date when the last service in the billing period was provided. Payment shall not be made if invoices and timesheets are received after this 30-day period.

77.30(18) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS health and disability waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, home-delivered meals, or personal emergency response.

a. *Definitions.*

"Major incident" means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;

2. Results in the death of any person;

3. Requires emergency mental health treatment for the consumer;

4. Requires the intervention of law enforcement;

5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;

6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph "1," "2," or "3"; or

7. Involves a consumer's location being unknown by provider staff who are assigned protective oversight.

"Minor incident" means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;

2. Results in bruising;

3. Results in seizure activity;

4. Results in injury to self, to others, or to property; or

5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member's supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

c. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member's supervisor.
2. The consumer or the consumer's legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider's service provision. Notification to the guardian, if any, is always required.
3. The consumer's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 0757C, IAB 5/29/13, effective 8/1/13; ARC 1149C, IAB 10/30/13, effective 1/1/14]

441—77.31(249A) Occupational therapists. Occupational therapists are eligible to participate if they are licensed and in private practice independent of the administrative and professional control of an employer such as a physician, institution, or rehabilitation agency. Licensed occupational therapists in an independent group practice are eligible to enroll.

77.31(1) Occupational therapists in other states are eligible to participate if they are licensed in that state and meet the Medicare criteria for enrollment.

77.31(2) Occupational therapists who provide services to Medicaid members who are also Medicare beneficiaries must be enrolled in the Medicare program.

This rule is intended to implement Iowa Code section 249A.4.

441—77.32(249A) Hospice providers. Hospice providers are eligible to participate in the Medicaid program providing they are certified to participate in the Medicare program.

This rule is intended to implement Iowa Code section 249A.4.

441—77.33(249A) HCBS elderly waiver service providers. HCBS elderly waiver services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider. The following providers shall be eligible to participate in the Medicaid HCBS elderly waiver program if they meet the standards in subrule 77.33(22) and also meet the standards set forth below for the service to be provided:

77.33(1) Adult day care providers. Adult day care providers shall be agencies that are certified by the department of inspections and appeals as being in compliance with the standards for adult day services programs at 481—Chapter 70.

77.33(2) Emergency response system providers. Emergency response system providers must meet the following standards:

a. The agency shall provide an electronic component to transmit a coded signal via digital equipment over telephone lines to a central monitoring station. The central monitoring station must operate receiving equipment and be fully staffed by trained attendants, 24 hours a day, seven days per week. The attendants must process emergency calls and ensure the timely notification of appropriate emergency resources to be dispatched to the person in need.

b. The agency, parent agency, institution or corporation shall have the necessary legal authority to operate in conformity with federal, state and local laws and regulations.

c. There shall be a governing authority which is responsible for establishing policy and ensuring effective control of services and finances. The governing authority shall employ or contract for an agency administrator to whom authority and responsibility for overall agency administration are delegated.

d. The agency or institution shall be in compliance with all legislation relating to prohibition of discriminatory practices.

e. There shall be written policies and procedures established to explain how the service operates, agency responsibilities, client responsibilities and cost information.

77.33(3) Home health aide providers. Home health aide providers shall be agencies certified to participate in the Medicare program as home health agencies.

77.33(4) Homemaker providers. Homemaker providers shall be agencies that are:

a. Certified as a home health agency under Medicare, or

b. Authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

77.33(5) Nursing care. Nursing care providers shall be agencies which are certified to participate in the Medicare program as home health agencies.

77.33(6) Respite care providers.

a. The following agencies may provide respite services:

(1) Home health agencies that are certified to participate in the Medicare program.

(2) Nursing facilities and hospitals enrolled as providers in the Iowa Medicaid program.

(3) Camps certified by the American Camping Association.

(4) Respite providers certified under the home- and community-based services intellectual disability waiver.

(5) Home care agencies that meet the conditions of participation set forth in subrule 77.33(4).

(6) Adult day care providers that meet the conditions set forth in subrule 77.33(1).

(7) Assisted living programs certified by the department of inspections and appeals.

b. Respite providers shall meet the following conditions:

(1) Providers shall maintain the following information that shall be updated at least annually:

1. The consumer's name, birth date, age, and address and the telephone number of the spouse, guardian or primary caregiver.
2. An emergency medical care release.
3. Emergency contact telephone numbers such as the number of the consumer's physician and the spouse, guardian, or primary caregiver.
4. The consumer's medical issues, including allergies.
5. The consumer's daily schedule which includes the consumer's preferences in activities or foods or any other special concerns.

(2) Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered. Home health agencies must follow Medicare regulations for medication dispensing.

All medications shall be stored in their original containers, with the accompanying physician's or pharmacist's directions and label intact. Medications shall be stored so they are inaccessible to consumers and the public. Nonprescription medications shall be labeled with the consumer's name.

In the case of medications that are administered on an ongoing, long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription.

(3) Policies shall be developed for:

1. Notifying the spouse, guardian, or primary caregiver of any injuries or illnesses that occur during respite provision. A spouse's, guardian's or primary caregiver's signature is required to verify receipt of notification.

2. Requiring the spouse, guardian or primary caregiver to notify the respite provider of any injuries or illnesses that occurred prior to respite provision.

3. Documenting activities and times of respite. This documentation shall be made available to the spouse, guardian or primary caregiver upon request.

4. Ensuring the safety and privacy of the individual. Policies shall at a minimum address threat of fire, tornado, or flood and bomb threats.

c. A facility providing respite under this subrule shall not exceed the facility's licensed capacity, and services shall be provided in locations consistent with licensure.

d. Respite provided outside the consumer's home or the facility covered by the licensure, certification, accreditation, or contract must be approved by the spouse, guardian or primary caregiver and the interdisciplinary team and must be consistent with the way the location is used by the general public. Respite in these locations shall not exceed 72 continuous hours.

77.33(7) *Chore providers.* The following providers may provide chore services:

- a. Home health agencies certified under Medicare.

- b. Community action agencies as designated in Iowa Code section 216A.93.

- c. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

- d. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

- e. Providers that were enrolled as chore providers as of June 30, 2010, based on a subcontract with or letter of approval from an area agency on aging.

- f. Community businesses that are engaged in the provision of chore services and that:

- (1) Have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations, and

- (2) Submit verification of current liability and workers' compensation coverage.

77.33(8) *Home-delivered meals.* The following providers may provide home-delivered meals:

- a. Area agencies on aging as designated in 17—4.4(231). Home-delivered meals providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating the organization is qualified to provide home-delivered meals services may also provide home-delivered meals services.

- b. Community action agencies as designated in Iowa Code section 216A.93.

- c. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

- d. Restaurants licensed and inspected under Iowa Code chapter 137F.
- e. Hospitals enrolled as Medicaid providers.
- f. Home health aide providers meeting the standards set forth in subrule 77.33(3).
- g. Medical equipment and supply dealers certified to participate in the Medicaid program.
- h. Home care providers meeting the standards set forth in subrule 77.33(4).

77.33(9) *Home and vehicle modification providers.* The following providers may provide home and vehicle modification:

- a. Area agencies on aging as designated in 17—4.4(231).
- b. Community action agencies as designated in Iowa Code section 216A.93.
- c. Providers eligible to participate as home and vehicle modification providers under the health and disability waiver, enrolled as home and vehicle modification providers under the physical disability waiver, or certified as home and vehicle modification providers under the home- and community-based services intellectual disability or brain injury waiver.
- d. Community businesses that have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations, and that submit verification of current liability and workers' compensation coverage.

77.33(10) *Mental health outreach providers.* Community mental health centers or other mental health providers accredited by the mental health and developmental disabilities commission pursuant to 441—Chapter 24 may provide mental health outreach services.

77.33(11) *Transportation providers.* The following providers may provide transportation:

- a. Area agencies on aging as designated in 17—4.4(231). Transportation providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating the organization is qualified to provide transportation services may also provide transportation services.
- b. Community action agencies as designated in Iowa Code section 216A.93.
- c. Regional transit agencies as recognized by the Iowa department of transportation.
- d. Rescinded IAB 3/10/99, effective 5/1/99.
- e. Nursing facilities licensed pursuant to Iowa Code chapter 135C.
- f. Transportation providers contracting with the nonemergency medical transportation contractor.

77.33(12) *Nutritional counseling.* The following providers may provide nutritional counseling by a dietitian licensed under 645—Chapter 81:

- a. Hospitals enrolled as Medicaid providers.
- b. Community action agencies as designated in Iowa Code section 216A.93.
- c. Nursing facilities licensed pursuant to Iowa Code chapter 135C.
- d. Home health agencies certified by Medicare.
- e. Independent licensed dietitians.

77.33(13) *Assistive device providers.* The following providers may provide assistive devices:

- a. Medicaid-enrolled medical equipment and supply dealers.
- b. Area agencies on aging as designated according to department on aging rules 17—4.4(231) and 17—4.9(231).
- c. Providers that were enrolled as assistive device providers as of June 30, 2010, based on a contract with or letter of approval from an area agency on aging.
- d. Community businesses that are engaged in the provision of assistive devices and that:
 - (1) Have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations, and
 - (2) Submit verification of current liability and workers' compensation coverage.

77.33(14) *Senior companions.* Senior companion programs designated by the Corporation for National and Community Service may provide senior companion service.

77.33(15) *Consumer-directed attendant care providers.* The following providers may provide consumer-directed attendant care service:

- a. An individual who contracts with the member to provide attendant care service and who is:
 - (1) At least 18 years of age.

(2) Qualified by training or experience to carry out the member's plan of care pursuant to the department-approved case plan or individual comprehensive plan.

(3) Not the spouse of the member or a parent or stepparent of a member aged 17 or under.

(4) Not the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

b. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

c. Home health agencies which are certified to participate in the Medicare program.

d. Chore providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating that the organization is qualified to provide chore services.

e. Community action agencies as designated in Iowa Code section 216A.93.

f. Providers certified under an HCBS waiver for supported community living.

g. Assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.

h. Adult day service providers that are certified by the department of inspections and appeals under 481—Chapter 70.

77.33(16) *Financial management service.* Consumers who elect the consumer choices option shall work with a financial institution that meets the qualifications in subrule 77.30(13).

77.33(17) *Independent support brokerage.* Consumers who elect the consumer choices option shall work with an independent support broker who meets the qualifications in subrule 77.30(14).

77.33(18) *Self-directed personal care.* Consumers who elect the consumer choices option may choose to purchase self-directed personal care services from an individual or business that meets the requirements in subrule 77.30(15).

77.33(19) *Individual-directed goods and services.* Consumers who elect the consumer choices option may choose to purchase individual-directed goods and services from an individual or business that meets the requirements in subrule 77.30(16).

77.33(20) *Self-directed community supports and employment.* Consumers who elect the consumer choices option may choose to purchase self-directed community supports and employment from an individual or business that meets the requirements in subrule 77.30(17).

77.33(21) *Case management providers.* A case management provider organization is eligible to participate in the Medicaid HCBS elderly waiver program if the organization meets the following standards:

a. The case management provider shall be an agency or individual that:

(1) Is accredited by the mental health, mental retardation, developmental disabilities, and brain injury commission as meeting the standards for case management services in 441—Chapter 24; or

(2) Is accredited through the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to provide case management; or

(3) Is accredited through the Council on Accreditation of Rehabilitation Facilities (CARF) to provide case management; or

(4) Is accredited through the Council on Quality and Leadership in Supports for People with Disabilities (CQL) to provide case management; or

(5) Is approved by the department on aging as meeting the standards for case management services in 17—Chapter 21; or

(6) Is authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services and that:

1. Meets the qualifications for case managers in 641—subrule 80.6(1); and

2. Provides a current IDPH local public health services contract number.

b. A case management provider shall not provide direct services to the consumer. The department and the Centers for Medicare and Medicaid Services deem the provision of direct services to case management consumers to be a conflict of interest. A person cannot be the first-line supervisor of both

case managers and direct service staff who are providing services to elderly waiver consumers. The provider must have written conflict of interest policies that include, but are not limited to:

- (1) Specific procedures to identify conflicts of interest.
- (2) Procedures to eliminate any conflict of interest that is identified.
- (3) Procedures for handling complaints of conflict of interest, including written documentation.

c. If the case management provider organization subcontracts case management services to another entity:

- (1) That entity must also meet the provider qualifications in this subrule; and
- (2) The contractor is responsible for verification of compliance.

77.33(22) Incident management and reporting. As a condition of participation in the medical assistance program, HCBS elderly waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of assistive devices, chore service, goods and services purchased under the consumer choices option, home and vehicle modification, home-delivered meals, personal emergency response, or transportation.

a. *Definitions.*

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“Minor incident” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

77.33(23) Assisted living on-call service. Assisted living on-call service providers shall be assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7936B**, IAB 7/1/09, effective 9/1/09; **ARC 9314B**, IAB 12/29/10, effective 3/1/11; **ARC 0545C**, IAB 1/9/13, effective 3/1/13; **ARC 0757C**, IAB 5/29/13, effective 8/1/13; **ARC 1071C**, IAB 10/2/13, effective 10/1/13]

441—77.34(249A) HCBS AIDS/HIV waiver service providers. HCBS AIDS/HIV waiver services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider. The following providers shall be eligible to participate in the Medicaid HCBS AIDS/HIV waiver program if they meet the standards in subrule 77.34(14) and also meet the standards set forth below for the service to be provided:

77.34(1) Counseling providers. Counseling providers shall be:

a. Agencies which are certified under the community mental health center standards established by the mental health and developmental disabilities commission, set forth in 441—Chapter 24, Divisions I and III.

b. Agencies which are licensed as meeting the hospice standards and requirements set forth in department of inspections and appeals rules 481—Chapter 53 or which are certified to meet the standards under the Medicare program for hospice programs.

c. Agencies which are accredited under the mental health service provider standards established by the mental health and developmental disabilities commission, set forth in 441—Chapter 24, Divisions I and IV.

77.34(2) Home health aide providers. Home health aide providers shall be agencies which are certified to participate in the Medicare program.

77.34(3) Homemaker providers. Homemaker providers shall be agencies that are:

- a. Certified as a home health agency under Medicare, or
- b. Authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

77.34(4) Nursing care providers. Nursing care providers shall be agencies which are certified to meet the standards under the Medicare program for home health agencies.

77.34(5) Respite care providers.

- a. The following agencies may provide respite services:
 - (1) Home health agencies that are certified to participate in the Medicare program.
 - (2) Nursing facilities, intermediate care facilities for the mentally retarded, or hospitals enrolled as providers in the Iowa Medicaid program.
 - (3) Respite providers certified under the home- and community-based services intellectual disability or brain injury waiver.
 - (4) Group living foster care facilities for children licensed by the department according to 441—Chapters 112 and 114 to 116 and child care centers licensed according to 441—Chapter 109.
 - (5) Camps certified by the American Camping Association.
 - (6) Home care agencies that meet the conditions of participation set forth in subrule 77.34(3).
 - (7) Adult day care providers that meet the conditions of participation set forth in subrule 77.34(7).
 - (8) Assisted living programs certified by the department of inspections and appeals.
- b. Respite providers shall meet the following conditions:
 - (1) Providers shall maintain the following information that shall be updated at least annually:
 1. The consumer's name, birth date, age, and address and the telephone number of each parent, guardian or primary caregiver.
 2. An emergency medical care release.
 3. Emergency contact telephone numbers such as the number of the consumer's physician and the parents, guardian, or primary caregiver.
 4. The consumer's medical issues, including allergies.
 5. The consumer's daily schedule which includes the consumer's preferences in activities or foods or any other special concerns.
 - (2) Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered. Home health agencies must follow Medicare regulations for medication dispensing.

All medications shall be stored in their original containers, with the accompanying physician's or pharmacist's directions and label intact. Medications shall be stored so they are inaccessible to consumers and the public. Nonprescription medications shall be labeled with the consumer's name.

In the case of medications that are administered on an ongoing, long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription.

(3) Policies shall be developed for:

1. Notifying the parent, guardian or primary caregiver of any injuries or illnesses that occur during respite provision. A parent's, guardian's or primary caregiver's signature is required to verify receipt of notification.
2. Requiring the parent, guardian, or primary caregiver to notify the respite provider of any injuries or illnesses that occurred prior to respite provision.
3. Documenting activities and times of respite. This documentation shall be made available to the parent, guardian or primary caregiver upon request.

4. Ensuring the safety and privacy of the individual. Policies shall at a minimum address threat of fire, tornado, or flood and bomb threats.

c. A facility providing respite under this subrule shall not exceed the facility's licensed capacity, and services shall be provided in locations consistent with licensure.

d. Respite provided outside the consumer's home or the facility covered by the licensure, certification, accreditation, or contract must be approved by the parent, guardian or primary caregiver and the interdisciplinary team and must be consistent with the way the location is used by the general public. Respite in these locations shall not exceed 72 continuous hours.

77.34(6) *Home-delivered meals.* The following providers may provide home-delivered meals:

a. Home health aide providers meeting the standards set forth in subrule 77.34(2).

b. Home care providers meeting the standards set forth in subrule 77.34(3).

c. Hospitals enrolled as Medicaid providers.

d. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

e. Restaurants licensed and inspected under Iowa Code chapter 137F.

f. Community action agencies as designated in Iowa Code section 216A.93. Home-delivered meals providers subcontracting with community action agencies or with letters of approval from the community action agencies stating the organization is qualified to provide home-delivered meals services may also provide home-delivered meals services.

g. Area agencies on aging as designated in 17—4.4(231). Home-delivered meals providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating the organization is qualified to provide home-delivered meals services may also provide home-delivered meals services.

h. Medical equipment and supply dealers certified to participate in the Medicaid program.

77.34(7) *Adult day care providers.* Adult day care providers shall be agencies that are certified by the department of inspections and appeals as being in compliance with the standards for adult day services programs at 481—Chapter 70.

77.34(8) *Consumer-directed attendant care providers.* The following providers may provide consumer-directed attendant care service:

a. An individual who contracts with the member to provide attendant care service and who is:

(1) At least 18 years of age.

(2) Qualified by training or experience to carry out the member's plan of care pursuant to the department-approved case plan or individual comprehensive plan.

(3) Not the spouse of the member or a parent or stepparent of a member aged 17 or under.

(4) Not the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

b. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

c. Home health agencies which are certified to participate in the Medicare program.

d. Chore providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating that the organization is qualified to provide chore services.

e. Community action agencies as designated in Iowa Code section 216A.93.

f. Providers certified under an HCBS waiver for supported community living.

g. Assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.

h. Adult day service providers that are certified by the department of inspections and appeals under 481—Chapter 70.

77.34(9) *Financial management service.* Consumers who elect the consumer choices option shall work with a financial institution that meets the qualifications in subrule 77.30(13).

77.34(10) *Independent support brokerage.* Consumers who elect the consumer choices option shall work with an independent support broker who meets the qualifications in subrule 77.30(14).

77.34(11) *Self-directed personal care.* Consumers who elect the consumer choices option may choose to purchase self-directed personal care services from an individual or business that meets the requirements in subrule 77.30(15).

77.34(12) *Individual-directed goods and services.* Consumers who elect the consumer choices option may choose to purchase individual-directed goods and services from an individual or business that meets the requirements in subrule 77.30(16).

77.34(13) *Self-directed community supports and employment.* Consumers who elect the consumer choices option may choose to purchase self-directed community supports and employment from an individual or business that meets the requirements in subrule 77.30(17).

77.34(14) *Incident management and reporting.* As a condition of participation in the medical assistance program, HCBS AIDS/HIV waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. **EXCEPTION:** The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or to home-delivered meals.

a. Definitions.

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“Minor incident” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. **EXCEPTION:** Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 1149C, IAB 10/30/13, effective 1/1/14]

441—77.35(249A) Federally qualified health centers. Federally qualified health centers are eligible to participate in the Medicaid program when the Centers for Medicare and Medicaid Services has notified the Medicaid program of their eligibility as allowed by Section 6404(b) of Public Law 101-239.

This rule is intended to implement Iowa Code section 249A.4.

441—77.36(249A) Advanced registered nurse practitioners. Advanced registered nurse practitioners are eligible to participate in the Medicaid program if they are duly licensed and registered by the state of Iowa as advanced registered nurse practitioners certified pursuant to board of nursing rules 655—Chapter 7.

77.36(1) Advanced registered nurse practitioners in another state shall be eligible to participate if they are duly licensed and registered in that state as advanced registered nurse practitioners with certification in a practice area consistent with board of nursing rules 655—Chapter 7.

77.36(2) Advanced registered nurse practitioners who have been certified eligible to participate in Medicare shall be considered as having met these guidelines.

77.36(3) Licensed nurse anesthetists who have graduated from a nurse anesthesia program meeting the standards set forth by a national association of nurse anesthetists within the past 18 months and who are awaiting initial certification by a national association of nurse anesthetists approved by the board of nursing shall be considered as having met these guidelines.

This rule is intended to implement Iowa Code section 249A.4.

441—77.37(249A) Home- and community-based services intellectual disability waiver service providers. Providers shall be eligible to participate in the Medicaid HCBS intellectual disability waiver program if they meet the requirements in this rule and the subrules applicable to the individual service.

The standards in subrule 77.37(1) apply only to providers of supported employment, respite providers certified according to subparagraph 77.37(15)“a”(8), and providers of supported community living services that are not residential-based. The standards and certification processes in subrules

77.37(2) through 77.37(7) and 77.37(9) through 77.37(12) apply only to supported employment providers and non-residential-based supported community living providers.

The requirements in subrule 77.37(13) apply to all providers. EXCEPTION: A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider and is not subject to the review requirements in subrule 77.37(13). Also, services must be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. Consumer-directed attendant care and interim medical monitoring and treatment providers must be at least 18 years of age.

77.37(1) Organizational standards (Outcome 1). Organizational outcome-based standards for home- and community-based services intellectual disability providers are as follows:

a. The organization demonstrates the provision and oversight of high-quality supports and services to consumers.

b. The organization demonstrates a defined mission commensurate with consumer's needs, desires, and abilities.

c. The organization establishes and maintains fiscal accountability.

d. The organization has qualified staff commensurate with the needs of the consumers they serve. These staff demonstrate competency in performing duties and in all interactions with clients.

e. The organization provides needed training and supports to its staff. This training includes at a minimum:

(1) Consumer rights.

(2) Confidentiality.

(3) Provision of consumer medication.

(4) Identification and reporting of child and dependent adult abuse.

(5) Individual consumer support needs.

f. The organization has a systematic, organizationwide, planned approach to designing, measuring, evaluating, and improving the level of its performance. The organization:

(1) Measures and assesses organizational activities and services annually.

(2) Gathers information from consumers, family members, and staff.

(3) Conducts an internal review of consumer service records, including all major and minor incident reports according to subrule 77.37(8).

(4) Tracks incident data and analyzes trends annually to assess the health and safety of consumers served by the organization.

(5) Identifies areas in need of improvement.

(6) Develops a plan to address the areas in need of improvement.

(7) Implements the plan and documents the results.

g. Consumers and their legal representatives have the right to appeal the provider's implementation of the 20 outcomes, or staff or contractual person's action which affects the consumer. The provider shall distribute the policies for consumer appeals and procedures to consumers.

h. The provider shall have written policies and procedures and a staff training program for the identification and reporting of child and dependent adult abuse to the department pursuant to 441—Chapters 175 and 176.

i. The governing body has an active role in the administration of the agency.

j. The governing body receives and uses input from a wide range of local community interests and consumer representation and provides oversight that ensures the provision of high-quality supports and services to consumers.

77.37(2) Rights and dignity. Outcome-based standards for rights and dignity are as follows:

a. (Outcome 2) Consumers are valued.

- b. (Outcome 3) Consumers live in positive environments.
- c. (Outcome 4) Consumers work in positive environments.
- d. (Outcome 5) Consumers exercise their rights and responsibilities.
- e. (Outcome 6) Consumers have privacy.
- f. (Outcome 7) When there is a need, consumers have support to exercise and safeguard their rights.
- g. (Outcome 8) Consumers decide which personal information is shared and with whom.
- h. (Outcome 9) Consumers make informed choices about where they work.
- i. (Outcome 10) Consumers make informed choices on how they spend their free time.
- j. (Outcome 11) Consumers make informed choices about where and with whom they live.
- k. (Outcome 12) Consumers choose their daily routine.
- l. (Outcome 13) Consumers are a part of community life and perform varied social roles.
- m. (Outcome 14) Consumers have a social network and varied relationships.
- n. (Outcome 15) Consumers develop and accomplish personal goals.
- o. (Outcome 16) Management of consumers' money is addressed on an individualized basis.
- p. (Outcome 17) Consumers maintain good health.
- q. (Outcome 18) The consumer's living environment is reasonably safe in the consumer's home and community.
- r. (Outcome 19) The consumer's desire for intimacy is respected and supported.
- s. (Outcome 20) Consumers have an impact on the services they receive.

77.37(3) *Contracts with consumers.* The provider shall have written procedures which provide for the establishment of an agreement between the consumer and the provider.

a. The agreement shall define the responsibilities of the provider and the consumer, the rights of the consumer, the services to be provided to the consumer by the provider, all room and board and copay fees to be charged to the consumer and the sources of payment.

b. Contracts shall be reviewed at least annually.

77.37(4) *The right to appeal.* Consumers and their legal representatives have the right to appeal the provider's application of policies or procedures, or any staff or contractual person's action which affects the consumer. The provider shall distribute the policies for consumer appeals and procedures to consumers.

77.37(5) *Storage and provision of medication.* If the provider stores, handles, prescribes, dispenses or administers prescription or over-the-counter medications, the provider shall develop procedures for the storage, handling, prescribing, dispensing or administration of medication. For controlled substances, procedures shall be in accordance with department of inspections and appeals rule 481—63.18(135).

If the provider has a physician on staff or under contract, the physician shall review and document the provider's prescribed medication regime at least annually in accordance with current medical practice.

77.37(6) *Research.* If the provider conducts research involving human subjects, the provider shall have written policies and procedures for research which ensure the rights of consumers and staff.

77.37(7) *Abuse reporting requirements.* The provider shall have written policies and procedures and a staff training program for the identification and reporting of child and dependent adult abuse to the department pursuant to 441—Chapters 175 and 176.

77.37(8) *Incident management and reporting.* As a condition of participation in the medical assistance program, HCBS intellectual disability waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, personal emergency response, and transportation.

a. *Definitions.*

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;

2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“*Minor incident*” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff consumer’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until

the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

77.37(9) *Intake, admission, service coordination, discharge, and referral.*

a. The provider shall have written policies and procedures according to state and federal laws for intake, admission, service coordination, discharge and referral. Service coordination means activities designed to help individuals and families locate, access, and coordinate a network of supports and services that will allow them to live a full life in the community.

b. The provider shall ensure the rights of persons applying for services.

77.37(10) *Certification process.* Reviews of compliance with standards for initial certification and recertification shall be conducted by the department of human services' bureau of long-term care quality assurance staff. Certification carries no assurance that the approved provider will receive funding.

a. Rescinded IAB 9/1/04, effective 11/1/04.

b. Rescinded IAB 9/1/04, effective 11/1/04.

c. Rescinded IAB 9/1/04, effective 11/1/04.

d. The department may request any information from the prospective service provider which is considered pertinent to arriving at a certification decision. This may include, but is not limited to:

(1) Current accreditations, evaluations, inspections and reviews by regulatory and licensing agencies and associations.

(2) Fiscal capacity of the prospective provider to initiate and operate the specified programs on an ongoing basis.

77.37(11) *Initial certification.* The department shall review the application and accompanying information to see if the provider has the necessary framework to provide services in accordance with all applicable requirements and standards.

a. The department shall make a determination regarding initial certification within 60 days of receipt of the application and notify the provider in writing of the decision unless extended by mutual consent of the parties involved. Providers shall be responsible for notifying the appropriate county and the appropriate central point of coordination of the determination.

b. The decision of the department on initial certification of the providers shall be based on all relevant information, including:

(1) The application for status as an approved provider according to requirements of rules.

(2) A determination of the financial position of the prospective provider in relation to its ability to meet the stated need.

(3) The prospective provider's coordination of service design, development, and application with the applicable region and other interested parties.

(4) The prospective provider's written agreement to work cooperatively with the state, counties and regions to be served by the provider.

c. Providers applying for initial certification shall be offered technical assistance.

77.37(12) *Period of certification.* Provider certification shall become effective on the date identified on the certificate of approval and shall terminate in 270 calendar days, one year, or three calendar years from the month of issue. The renewal of certification shall be contingent upon demonstration of continued compliance with certification requirements.

a. Initial certification. Providers eligible for initial certification by the department shall be issued an initial certification for 270 calendar days based on documentation provided.

b. Recertification. After the initial certification, the level of certification shall be based on an on-site review unless the provider has been accredited for similar services by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities (CARF), the Council on Quality and Leadership in Supports for People with Disabilities (The Council), or the Council on Accreditation of Services for Families and Children (COA). The on-site reviews for supported community living and supported employment use interviews with consumers and

significant people in the consumer's life to determine whether or not the 20 individual value-based outcomes set forth in subrules 77.37(1) and 77.37(2) and corresponding processes are present for the consumer. Respite services are required to meet Outcome 1 and participate in satisfaction surveys.

Once the outcomes and processes have been determined for all the consumers in the sample, a review team then determines which of the 20 outcomes and processes are present for the provider. A specific outcome is present for the provider when the specific outcome is determined to be present for 75 percent or more of the consumers interviewed. A specific process is present for the provider when the process is determined to be present for 75 percent or more of the consumers interviewed. Since the processes are in the control of the provider and the outcomes are more in the control of the consumer, length of certification will be based more heavily on whether or not the processes are in place to help consumers obtain desired outcomes.

An exit conference shall be held with the organization to share preliminary findings of the certification review. A review report shall be written and sent to the provider within 30 calendar days unless the parties mutually agree to extend that time frame.

Provider certification shall become effective on the date identified on the Certificate of Approval, Form 470-3410, and shall terminate in 270 calendar days, one year, or three calendar years from the month of issue. The renewal of certification shall be contingent upon demonstration of continued compliance with certification requirements.

c. The department may issue four categories of recertification:

(1) Three-year certification with excellence. An organization is eligible for certification with excellence if the number of processes present is 18 or higher and the number of outcomes and corresponding processes present together is 12 or higher. Both criteria need to be met to receive three-year certification with excellence. Corrective actions may be required which may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.

(2) Three-year certification with follow-up monitoring. An organization is eligible for this type of certification if the number of processes present is 17 or higher and the number of outcomes and corresponding processes present together are 11 or higher. Both criteria need to be met to receive three-year certification. Corrective actions are required which may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.

(3) One-year certification. An organization is eligible for this type of certification when the number of processes present is 14 or higher and the number of outcomes and processes together is 9 or higher. Both criteria need to be met to receive one-year certification. One-year certification may also be given in lieu of longer certification when previously required corrective actions have not been implemented or completed. Corrective actions are required which may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.

(4) Probational certification. A probational certification may be issued to those providers who cannot meet requirements for a one-year certification. This time period shall be granted to the provider to establish and implement corrective actions and improvement activities. During this time period the department may require monitoring of the implementation of the corrective actions through on-site visits, written reports or technical assistance. Probational certification issued for 270 calendar days shall not be renewed or extended, and shall require a full on-site follow-up review to be completed. The provider shall be required to achieve at least a one-year certification status at the time of the follow-up review in order to maintain certification.

d. During the course of the review, if a team member encounters a situation that places a member in immediate jeopardy, the team member shall immediately notify the provider, the department, and other team members. "Immediate jeopardy" refers to circumstances where the life, health, or safety of a member will be severely jeopardized if the circumstances are not immediately corrected.

(1) The provider shall correct the situation within 24 to 48 hours. If the situation is not corrected within the prescribed time frame, that portion of the provider's services that was the subject of the

notification shall not be certified. The department shall be notified immediately to discontinue funding for that provider's service. If a member is in immediate jeopardy, the case manager or department service worker shall notify the county or region in the event the county or region is funding a service that may assist the member in the situation.

(2) If this action is appealed and the member, legal guardian, or attorney in fact under a durable power of attorney for health care wants to maintain the provider's services, funding can be reinstated. At that time the provider shall take appropriate action to ensure the life, health, and safety of the members deemed to be at risk as a result of the provider's inaction.

e. As a mandatory reporter, each team member shall be required to follow appropriate procedure in all cases where a condition reportable to child and adult protective services is observed.

f. The department may grant an extension to the period of approval for the following reasons:

(1) A delay in the department's approval decision which is beyond the control of the provider or department.

(2) A request for an extension from a provider to permit the provider to prepare and obtain department approval of corrective actions. The department shall establish the length of extensions on a case-by-case basis.

g. The department may revoke the provider's approval at any time for any of the following reasons:

(1) Findings of a site visit indicate that the provider has failed to implement the corrective actions submitted pursuant to paragraph 77.37(13)"*e.*"

(2) The provider has failed to provide information requested pursuant to paragraph 77.37(13)"*f.*"

(3) The provider refuses to allow the department to conduct a site visit pursuant to paragraph 77.37(13)"*h.*"

(4) There are instances of noncompliance with the standards which were not identified from information submitted on the application.

h. An approved provider shall immediately notify the department, applicable county, or region, the applicable mental health and developmental disabilities planning council, and other interested parties of a decision to withdraw from a home- and community-based services intellectual disability waiver service.

i. Following certification, any provider may request technical assistance from the department to bring into conformity those areas found in noncompliance with HCBS requirements. If multiple deficiencies are noted during a review, the department may require that technical assistance be provided to a provider to assist in the implementation of the provider's corrective actions. Providers may be given technical assistance as needed.

j. Appeals. Any adverse action can be appealed by the provider under 441—Chapter 7.

77.37(13) Review of providers. Reviews of compliance with standards as indicated in this chapter shall be conducted by designated members of the HCBS staff.

a. This review may include on-site case record audits; review of administrative procedures, clinical practices, personnel records, performance improvement systems and documentation; and interviews with staff, consumers, the board of directors, or others deemed appropriate, consistent with the confidentiality safeguards of state and federal laws.

b. A review visit shall be scheduled with the provider with additional reviews conducted at the discretion of the department.

c. The on-site review team will consist of designated members of the HCBS staff.

d. Following a certification review, the certification review team leader shall submit a copy of the department's written report of findings to the provider within 30 working days after completion of the certification review.

e. The provider shall develop a plan of corrective action, if applicable, identifying completion time frames for each review recommendation.

f. Providers required to make corrective actions and improvements shall submit the corrective action and improvement plan to the Bureau of Long-Term Care, 1305 East Walnut Street, Des Moines, Iowa 50319-0114, within 30 working days after the receipt of a report issued as a result of the review team's visit. The corrective actions may include: specific problem areas cited, corrective actions to be

implemented by the provider, dates by which each corrective measure will be completed, and quality assurance and improvement activities to measure and ensure continued compliance.

g. The department may request the provider to supply subsequent reports on implementation of a corrective action plan submitted pursuant to 77.37(13)“e” and 77.37(13)“f.”

h. The department may conduct a site visit to verify all or part of the information submitted.

77.37(14) Supported community living providers.

a. The department will contract only with public or private agencies to provide the supported community living service. The department does not recognize individuals as service providers under the supported community living program.

b. Providers of services meeting the definition of foster care shall also be licensed according to applicable 441—Chapters 108, 112, 114, 115, and 116.

c. Providers of service may employ or contract with individuals meeting the definition of foster family homes to provide supported community living services. These individuals shall be licensed according to applicable 441—Chapters 112 and 113.

d. All supported community living providers shall meet the following requirements:

(1) The provider shall demonstrate how the provider will meet the outcomes and processes in rule 441—77.37(249A) for each of the consumers being served. The provider shall supply timelines showing how the provider will come into compliance with rules 441—77.37(249A), 441—78.41(249A), and 441—83.60(249A) to 441—83.70(249A) and 441—subrule 79.1(15) within one year of certification. These timelines shall include:

1. Implementation of necessary staff training and consumer input.
2. Implementation of provider system changes to allow for flexibility in staff duties, services based on what each individual needs, and removal of housing as part of the service.

(2) The provider shall demonstrate that systems are in place to measure outcomes and processes for individual consumers before certification can be given.

e. The department shall approve living units designed to serve up to four persons except as necessary to prevent an overconcentration of supported community living units in a geographic area.

f. The department shall approve a living unit designed to serve five persons if both of the following conditions are met:

(1) Approval will not result in an overconcentration of supported community living units in a geographic area.

(2) The county in which the living unit is located provides to the bureau of long-term care verification in writing that the approval is needed to address one or more of the following issues:

1. The quantity of services currently available in the county is insufficient to meet the need;
2. The quantity of affordable rental housing in the county is insufficient to meet the need; or
3. Approval will result in a reduction in the size or quantity of larger congregate settings.

77.37(15) Respite care providers.

a. The following agencies may provide respite services:

(1) Group living foster care facilities for children licensed by the department according to 441—Chapters 112 and 114 to 116 and child care centers licensed according to 441—Chapter 109.

(2) Nursing facilities, intermediate care facilities for the mentally retarded, and hospitals enrolled as providers in the Iowa Medicaid program.

(3) Residential care facilities for persons with mental retardation licensed by the department of inspections and appeals.

(4) Home health agencies that are certified to participate in the Medicare program.

(5) Camps certified by the American Camping Association.

(6) Adult day care providers that meet the conditions of participation set forth in subrule 77.37(25).

(7) Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

(8) Agencies certified by the department to provide respite services in the consumer’s home that meet the requirements of 77.37(1) and 77.37(3) through 77.37(9).

- (9) Assisted living programs certified by the department of inspections and appeals.
 - b. Respite providers shall meet the following conditions:
 - (1) Providers shall maintain the following information that shall be updated at least annually:
 1. The consumer's name, birth date, age, and address and the telephone number of each parent, guardian or primary caregiver.
 2. An emergency medical care release.
 3. Emergency contact telephone numbers such as the number of the consumer's physician and the parents, guardian, or primary caregiver.
 4. The consumer's medical issues, including allergies.
 5. The consumer's daily schedule which includes the consumer's preferences in activities or foods or any other special concerns.
 - (2) Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered. Home health agencies must follow Medicare regulations for medication dispensing.

All medications shall be stored in their original containers, with the accompanying physician's or pharmacist's directions and label intact. Medications shall be stored so they are inaccessible to consumers and the public. Nonprescription medications shall be labeled with the consumer's name.

In the case of medications that are administered on an ongoing, long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription.
 - (3) Policies shall be developed for:
 1. Notifying the parent, guardian or primary caregiver of any injuries or illnesses that occur during respite provision. A parent's, guardian's or primary caregiver's signature is required to verify receipt of notification.
 2. Requiring the parent, guardian or primary caregiver to notify the respite provider of any injuries or illnesses that occurred prior to respite provision.
 3. Documenting activities and times of respite. This documentation shall be made available to the parent, guardian or primary caregiver upon request.
 4. Ensuring the safety and privacy of the individual. Policies shall at a minimum address threat of fire, tornado, or flood and bomb threats.
 - c. A facility providing respite under this subrule shall not exceed the facility's licensed capacity, and services shall be provided in locations consistent with licensure.
 - d. Respite provided outside the consumer's home or the facility covered by the licensure, certification, accreditation, or contract must be approved by the parent, guardian or primary caregiver and the interdisciplinary team and must be consistent with the way the location is used by the general public. Respite in these locations shall not exceed 72 continuous hours.
- 77.37(16) Supported employment providers.**
- a. The following agencies may provide supported employment services:
 - (1) An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities as an organizational employment service provider, a community employment service provider, or a provider of a similar service.
 - (2) An agency that is accredited by the Council on Accreditation of Services for Families and Children for similar services.
 - (3) An agency that is accredited by the Joint Commission on Accreditation of Healthcare Organizations for similar services.
 - (4) An agency that is accredited by the Council on Quality and Leadership in Supports for People with Disabilities for similar services.
 - (5) An agency that is accredited by the International Center for Clubhouse Development.
 - b. Providers responsible for the payroll of members shall have policies that ensure compliance with state and federal labor laws and regulations, which include, but are not limited to:
 - (1) Member vacation, sick leave and holiday compensation.
 - (2) Procedures for payment schedules and pay scale.
 - (3) Procedures for provision of workers' compensation insurance.

(4) Procedures for the determination and review of commensurate wages.

c. The department will contract only with public or private agencies to provide supported employment services. The department does not recognize individuals as service providers under the supported employment program.

77.37(17) Home and vehicle modification providers. The following providers may provide home and vehicle modification:

a. Providers certified to participate as supported community living service providers under the home- and community-based services intellectual disability or brain injury waiver.

b. Providers eligible to participate as home and vehicle modification providers under the elderly or health and disability waiver, enrolled as home and vehicle modification providers under the physical disability waiver, or certified as home and vehicle modification providers under the brain injury waiver.

c. Community businesses that have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations and that submit verification of current liability and workers' compensation insurance.

77.37(18) Personal emergency response system providers. Personal emergency response system providers shall be agencies which meet the conditions of participation set forth in subrule 77.33(2) to maintain certification.

77.37(19) Nursing providers. Nursing providers shall be agencies that are certified to participate in the Medicare program as home health agencies.

77.37(20) Home health aide providers. Home health aide providers shall be agencies which are certified to participate in the Medicare program as home health agencies and which have an HCBS agreement with the department.

77.37(21) Consumer-directed attendant care providers. The following providers may provide consumer-directed attendant care service:

a. An individual who contracts with the member to provide attendant care service and who is:

(1) At least 18 years of age.

(2) Qualified by training or experience to carry out the member's plan of care pursuant to the department-approved case plan or individual comprehensive plan.

(3) Not the spouse of the member or a parent or stepparent of a member aged 17 or under.

(4) Not the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

b. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

c. Home health agencies which are certified to participate in the Medicare program.

d. Chore providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating that the organization is qualified to provide chore services.

e. Community action agencies as designated in Iowa Code section 216A.93.

f. Providers certified under an HCBS waiver for supported community living.

g. Assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.

h. Adult day service providers that are certified by the department of inspections and appeals under 481—Chapter 70.

77.37(22) Interim medical monitoring and treatment providers.

a. The following providers may provide interim medical monitoring and treatment services:

(1) Home health agencies certified to participate in the Medicare program.

(2) Supported community living providers certified according to subrule 77.37(14) or 77.39(13).

b. Staff requirements. Staff members providing interim medical monitoring and treatment services to members shall meet all of the following requirements:

(1) Be at least 18 years of age.

(2) Not be the spouse of the member or a parent or stepparent of the member if the member is aged 17 or under.

(3) Not be a usual caregiver of the member.

(4) Be qualified by training or experience to provide medical intervention or intervention in a medical emergency necessary to carry out the member's plan of care. The training or experience required must be determined by the member's usual caregivers and a licensed medical professional on the member's interdisciplinary team and must be documented in the member's service plan.

c. Service documentation. Providers shall maintain clinical and fiscal records necessary to fully disclose the extent of services furnished to members. Records shall specify by service date the procedures performed, together with information concerning progress of treatment.

77.37(23) *Residential-based supported community living service providers.*

a. The department shall contract only with public or private agencies to provide residential-based supported community living services.

b. Subject to the requirements of this rule, the following agencies may provide residential-based supported community living services:

(1) Agencies licensed as group living foster care facilities under 441—Chapter 114.

(2) Agencies licensed as residential facilities for mentally retarded children under 441—Chapter 116.

(3) Other agencies providing residential-based supported community living services that meet the following conditions:

1. The agency must provide orientation training on the agency's purpose, policies, and procedures within one month of hire or contracting for all employed and contracted treatment staff and must provide 24 hours of training during the first year of employment or contracting. The agency must also provide at least 12 hours of training per year after the first year of employment for all employed and contracted treatment staff. Annual training shall include, at a minimum, training on children's mental retardation and developmental disabilities services and children's mental health issues. Identification and reporting of child abuse shall be covered in training at least every five years, in accordance with Iowa Code section 232.69.

2. The agency must have standards for the rights and dignity of children that are age-appropriate. These standards shall include the following:

- Children, their families, and their legal representatives decide what personal information is shared and with whom.

- Children are a part of family and community life and perform varied social roles.
- Children have family connections, a social network, and varied relationships.
- Children develop and accomplish personal goals.
- Children are valued.
- Children live in positive environments.
- Children exercise their rights and responsibilities.
- Children make informed choices about how they spend their free time.
- Children choose their daily routine.

3. The agency must use methods of self-evaluation by which:

- Past performance is reviewed.
- Current functioning is evaluated.
- Plans are made for the future based on the review and evaluation.

4. The agency must have a governing body that receives and uses input from a wide range of local community interests and consumer representatives and provides oversight that ensures the provision of high-quality supports and services to children.

5. Children, their parents, and their legal representatives must have the right to appeal the service provider's application of policies or procedures or any staff person's action that affects the consumer. The service provider shall distribute the policies for consumer appeals and procedures to children, their parents, and their legal representatives.

c. As a condition of participation, all providers of residential-based supported community living services must have the following on file:

(1) Current accreditations, evaluations, inspections, and reviews by applicable regulatory and licensing agencies and associations.

(2) Documentation of the fiscal capacity of the provider to initiate and operate the specified programs on an ongoing basis.

(3) The provider's written agreement to work cooperatively with the department.

d. As a condition of participation, all providers of residential-based supported community living services must develop, review, and revise service plans for each child, as follows:

(1) The service plan shall be developed in collaboration with the social worker or case manager, child, family, and, if applicable, the foster parents, unless a treatment rationale for the lack of involvement of one of these parties is documented in the plan. The service provider shall document the dates and content of the collaboration on the service plan. The service provider shall provide a copy of the service plan to the family and the case manager, unless otherwise ordered by a court of competent jurisdiction.

(2) Initial service plans shall be developed after services have been authorized and within 30 calendar days of initiating services.

(3) The service plan shall identify the following:

1. Strengths and needs of the child.

2. Goals to be achieved to meet the needs of the child.

3. Objectives for each goal that are specific, measurable, and time-limited and include indicators of progress toward each goal.

4. Specific service activities to be provided to achieve the objectives.

5. The persons responsible for providing the services. When daily living and social skills development is provided in a group care setting, designation may be by job title.

6. Date of service initiation and date of individual service plan development.

7. Service goals describing how the child will be reunited with the child's family and community.

(4) Individuals qualified to provide all services identified in the service plan shall review the services identified in the service plan to ensure that the services are necessary, appropriate, and consistent with the identified needs of the child, as listed on Form 470-3273, Mental Retardation Functional Assessment Tool.

(5) The service worker or case manager shall review all service plans to determine progress toward goals and objectives 90 calendar days from the initiation of services and every 90 calendar days thereafter for the duration of the services.

At a minimum, the provider shall submit written reports to the service worker or case manager at six-month intervals and when changes to the service plan are needed.

(6) The individual service plan shall be revised when any of the following occur:

1. Service goals or objectives have been achieved.

2. Progress toward goals and objectives is not being made.

3. Changes have occurred in the identified service needs of the child, as listed on Form 470-3273, Mental Retardation Functional Assessment Tool.

4. The service plan is not consistent with the identified service needs of the child, as listed in the service plan.

(7) The service plan shall be signed and dated by qualified staff of each reviewing provider after each review and revision.

(8) Any revisions of the service plan shall be made in collaboration with the child, family, case manager, and, if applicable, the foster parents and shall reflect the needs of the child. The service provider shall provide a copy of the revised service plan to the family and case manager, unless otherwise ordered by a court of competent jurisdiction.

e. The residential-based supportive community living service provider shall also furnish residential-based living units for all recipients of the residential-based supported community living services. Except as provided herein, living units provided may be of no more than four beds. Service providers who receive approval from the bureau of long-term care may provide living units of up to eight beds. The bureau shall approve five- to eight-bed living units only if all of the following conditions are met:

- (1) Rescinded IAB 8/7/02, effective 10/1/02.
- (2) There is a need for the service to be provided in a five- to eight-person living unit instead of a smaller living unit, considering the location of the programs in an area.
- (3) The provider supplies the bureau of long-term care with a written plan acceptable to the department that addresses how the provider will reduce its living units to four-bed units within a two-year period of time. This written plan shall include the following:
 1. How the transition will occur.
 2. What physical change will need to take place in the living units.
 3. How children and their families will be involved in the transitioning process.
 4. How this transition will affect children's social and educational environment.
 - f. Certification process and review of service providers.
- (1) The certification process for providers of residential-based supported community living services shall be pursuant to subrule 77.37(10).
- (2) The initial certification of residential-based supported community living services shall be pursuant to subrule 77.37(11).
- (3) Period and conditions of certification.
 1. Initial certification. Providers eligible for initial certification by the department shall be issued an initial certification for 270 calendar days, effective on the date identified on the certificate of approval, based on documentation provided.
 2. Recertification. After the initial certification, recertification shall be based on an on-site review and shall be contingent upon demonstration of compliance with certification requirements.

An exit conference shall be held with the provider to share preliminary findings of the recertification review. A review report shall be written and sent to the provider within 30 calendar days unless the parties mutually agree to extend that time frame.

Recertification shall become effective on the date identified on the Certificate of Approval, Form 470-3410, and shall terminate one year from the month of issuance.

Corrective actions may be required in connection with recertification and may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.
 3. Probational certification. Probational certification for 270 calendar days may be issued to a provider who cannot demonstrate compliance with all certification requirements on recertification review to give the provider time to establish and implement corrective actions and improvement activities.

During the probational certification period, the department may require monitoring of the implementation of the corrective actions through on-site visits, written reports, or technical assistance.

Probational certification shall not be renewed or extended and shall require a full on-site follow-up review to be completed. The provider must demonstrate compliance with all certification requirements at the time of the follow-up review in order to maintain certification.
 4. Immediate jeopardy. If, during the course of any review, a review team member encounters a situation that places a member in immediate jeopardy, the team member shall immediately notify the provider, the department, and other team members. "Immediate jeopardy" refers to circumstances where the life, health, or safety of a member will be severely jeopardized if the circumstances are not immediately corrected.

The provider shall correct the situation within 24 to 48 hours. If the situation is not corrected within the prescribed time frame, the provider shall not be certified. The department shall immediately discontinue funding for that provider's service. If this action is appealed and the member or legal guardian wants to maintain the provider's services, funding can be reinstated. At that time the provider shall take appropriate action to ensure the life, health, and safety of the members deemed to be at risk. The case manager or department service worker shall notify the county or region in the event the county or region is funding a service that may assist the member in the situation.
 5. Abuse reporting. As a mandatory reporter, each review team member shall follow appropriate procedure in all cases where a condition reportable to child and adult protective services is observed.

6. Extensions. The department shall establish the length of extensions on a case-by-case basis. The department may grant an extension to the period of certification for the following reasons:

- A delay in the department's approval decision exists which is beyond the control of the provider or department.
- A request for an extension is received from a provider to permit the provider to prepare and obtain department approval of corrective actions.

7. Revocation. The department may revoke the provider's approval at any time for any of the following reasons:

- The findings of a site visit indicate that the provider has failed to implement the corrective actions submitted pursuant to paragraph 77.37(13) "e" and numbered paragraph 77.37(23) "f"(3) "4."
- The provider has failed to provide information requested pursuant to paragraph 77.37(13) "f" and numbered paragraph 77.37(23) "f"(3) "4."
- The provider refuses to allow the department to conduct a site visit pursuant to paragraph 77.37(13) "h" and subparagraph 77.37(23) "f"(3).
- There are instances of noncompliance with the standards that were not identified from information submitted on the application.

8. Notice of intent to withdraw. An approved provider shall immediately notify the department, applicable county, the applicable mental health and developmental disabilities planning council, and other interested parties of a decision to withdraw as a provider of residential-based supported community living services.

9. Technical assistance. Following certification, any provider may request technical assistance from the department regarding compliance with program requirements. The department may require that technical assistance be provided to a provider to assist in the implementation of any corrective action plan.

10. Appeals. The provider can appeal any adverse action under 441—Chapter 7.

(4) Providers of residential-based supported community living services shall be subject to reviews of compliance with program requirements pursuant to subrule 77.37(13).

77.37(24) *Transportation service providers.* The following providers may provide transportation:

- a. Accredited providers of home- and community-based services.
- b. Regional transit agencies as recognized by the Iowa department of transportation.
- c. Transportation providers that contract with county governments.
- d. Community action agencies as designated in Iowa Code section 216A.93.
- e. Nursing facilities licensed under Iowa Code chapter 135C.
- f. Area agencies on aging as designated in rule 17—4.4(231), subcontractors of area agencies on aging, or organizations with letters of approval from the area agencies on aging stating that the organization is qualified to provide transportation services.
- g. Transportation providers contracting with the nonemergency medical transportation contractor.

77.37(25) *Adult day care providers.* Adult day care providers shall be agencies that are certified by the department of inspections and appeals as being in compliance with the standards for adult day services programs at 481—Chapter 70.

77.37(26) *Prevocational services providers.* Providers of prevocational services must be accredited by one of the following:

- a. The Commission on Accreditation of Rehabilitation Facilities as a work adjustment service provider or an organizational employment service provider.
- b. The Council on Quality and Leadership.

77.37(27) *Day habilitation providers.* Day habilitation services may be provided by:

- a. Agencies accredited by the Commission on Accreditation of Rehabilitation Facilities to provide services that qualify as day habilitation under 441—subrule 78.41(14).
- b. Agencies accredited by the Commission on Accreditation of Rehabilitation Facilities to provide other services that began providing services that qualify as day habilitation under 441—subrule 78.41(14) since their last accreditation survey. The agency may provide day habilitation services until the current

accreditation expires. When the current accreditation expires, the agency must qualify under paragraph “a” or “d.”

c. Agencies not accredited by the Commission on Accreditation of Rehabilitation Facilities that have applied to the Commission within the last 12 months for accreditation to provide services that qualify as day habilitation under 441—subrule 78.41(14). An agency that has not received accreditation within 12 months after application to the Commission is no longer a qualified provider.

d. Agencies accredited by the Council on Quality and Leadership.

e. Agencies that have applied to the Council on Quality and Leadership for accreditation within the last 12 months. An agency that has not received accreditation within 12 months after application to the Council is no longer a qualified provider.

77.37(28) *Financial management service.* Consumers who elect the consumer choices option shall work with a financial institution that meets the qualifications in subrule 77.30(13).

77.37(29) *Independent support brokerage.* Consumers who elect the consumer choices option shall work with an independent support broker who meets the qualifications in subrule 77.30(14).

77.37(30) *Self-directed personal care.* Consumers who elect the consumer choices option may choose to purchase self-directed personal care services from an individual or business that meets the requirements in subrule 77.30(15).

77.37(31) *Individual-directed goods and services.* Consumers who elect the consumer choices option may choose to purchase individual-directed goods and services from an individual or business that meets the requirements in subrule 77.30(16).

77.37(32) *Self-directed community supports and employment.* Consumers who elect the consumer choices option may choose to purchase self-directed community supports and employment from an individual or business that meets the requirements in subrule 77.30(17).

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 0191C, IAB 7/11/12, effective 7/1/12; ARC 0359C, IAB 10/3/12, effective 12/1/12; ARC 0757C, IAB 5/29/13, effective 8/1/13; ARC 1071C, IAB 10/2/13, effective 10/1/13; ARC 1149C, IAB 10/30/13, effective 1/1/14]

441—77.38(249A) *Assertive community treatment.* Services in the assertive community treatment (ACT) program shall be rendered by a multidisciplinary team composed of practitioners from the disciplines described in this rule. The team shall be under the clinical supervision of a psychiatrist. The program shall designate an individual team member who shall be responsible for administration of the program, including authority to sign documents and receive payment on behalf of the program.

77.38(1) *Minimum composition.* At a minimum, the team shall consist of a nurse, a mental health service provider, and a substance abuse treatment professional.

77.38(2) *Psychiatrists.* A psychiatrist on the team shall be a physician (MD or DO) who:

- a. Is licensed under 653—Chapter 9,
- b. Is certified as a psychiatrist by the American Board of Medical Specialties’ Board of Psychiatry and Neurology or by the American Osteopathic Board of Neurology and Psychiatry, and
- c. Has experience treating serious and persistent mental illness.

77.38(3) *Registered nurses.* A nurse on the team shall:

- a. Be licensed as a registered nurse under 655—Chapter 3, and
- b. Have experience treating persons with serious and persistent mental illness.

77.38(4) *Mental health service providers.* A mental health service provider on the team shall be:

- a. A mental health counselor or marital and family therapist who:
 - (1) Is licensed under 645—Chapter 31, and
 - (2) Has experience treating persons with serious and persistent mental illness; or
- b. A social worker who:
 - (1) Is licensed as a master or independent social worker under 645—Chapter 280, and
 - (2) Has experience treating persons with serious and persistent mental illness.

77.38(5) *Psychologists.* A psychologist on the team shall:

- a. Be licensed under 645—Chapter 240, and
- b. Have experience treating persons with serious and persistent mental illness.

77.38(6) Substance abuse treatment professionals. A substance abuse treatment professional on the team shall:

- a. Be an appropriately credentialed counselor pursuant to 641—paragraph 155.21(8) “i,” and
- b. Have at least three years of experience treating substance abuse.

77.38(7) Peer specialists. A peer specialist on the team shall be a person with serious and persistent mental illness who has met all requirements of a nationally standardized peer support training program, including at least 30 hours of training and satisfactory completion of an examination.

77.38(8) Community support specialists. A community support specialist on the team shall be a person who:

- a. Has a bachelor’s degree (BA or BS) in a human services field (sociology, social work, counseling, psychology, or human services), and
- b. Has experience supporting persons with serious and persistent mental illness.

77.38(9) Case managers. A case manager on the team shall be a person who:

- a. Has a bachelor’s degree (BA or BS) in a human services field (sociology, social work, counseling, psychology, or human services),
- b. Has experience managing care for persons with serious and persistent mental illness, and
- c. Meets the qualifications of “qualified case managers and supervisors” in rule 441—24.1(225C).

77.38(10) Advanced registered nurse practitioners. An advanced registered nurse practitioner on the team shall:

- a. Be licensed under 655—Chapter 7,
- b. Have a mental health certification, and
- c. Have experience treating serious and persistent mental illness.

77.38(11) Physician assistants. A physician assistant on the team shall:

- a. Be licensed under 645—Chapter 326,
- b. Have experience treating persons with serious and persistent mental illness, and
- c. Practice under the supervision of a psychiatrist.

This rule is intended to implement Iowa Code section 249A.4.

[ARC 9440B, IAB 4/6/11, effective 4/1/11]

441—77.39(249A) HCBS brain injury waiver service providers. Providers shall be eligible to participate in the Medicaid brain injury waiver program if they meet the requirements in this rule and the subrules applicable to the individual service. Beginning January 1, 2015, providers initially enrolling to deliver BI waiver services and each of their staff members involved in direct consumer service must have completed the department’s brain injury training modules one and two within 60 days from the beginning date of service provision, with the exception of staff members who are certified through the Academy of Certified Brain Injury Specialists (ACBIS) as a certified brain injury specialist (CBIS) or certified brain injury specialist trainer (CBIST), providers of home and vehicle modification, specialized medical equipment, transportation, personal emergency response, financial management, independent support brokerage, self-directed personal care, individual-directed goods and services, and self-directed community supports and employment. Providers enrolled to provide BI waiver services and each of their staff members involved in direct consumer service on or before December 31, 2014, shall be deemed to have completed the required training.

Services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider and is not subject to review under subrule 77.39(11). Consumer-directed attendant care and interim medical monitoring and treatment providers must be at least 18 years of age.

In addition, behavioral programming, supported community living, and supported employment providers shall meet the outcome-based standards set forth below in subrules 77.39(1) and 77.39(2) evaluated according to subrules 77.39(8) to 77.39(10), and the requirements of subrules 77.39(3) to 77.39(7). Respite providers shall also meet the standards in subrule 77.39(1).

77.39(1) *Organizational standards (Outcome 1).* Organizational outcome-based standards for HCBS BI providers are as follows:

a. The organization demonstrates the provision and oversight of high-quality supports and services to consumers.

b. The organization demonstrates a defined mission commensurate with consumers' needs, desires, and abilities.

c. The organization establishes and maintains fiscal accountability.

d. The organization has qualified staff commensurate with the needs of the consumers they serve. These staff demonstrate competency in performing duties and in all interactions with clients.

e. The organization provides needed training and supports to its staff. This training includes at a minimum:

(1) Consumer rights.

(2) Confidentiality.

(3) Provision of consumer medication.

(4) Identification and reporting of child and dependent adult abuse.

(5) Individual consumer support needs.

f. The organization has a systematic, organizationwide, planned approach to designing, measuring, evaluating, and improving the level of its performance. The organization:

(1) Measures and assesses organizational activities and services annually.

(2) Gathers information from consumers, family members, and staff.

(3) Conducts an internal review of consumer service records, including all major and minor incident reports according to subrule 77.37(8).

(4) Tracks incident data and analyzes trends annually to assess the health and safety of consumers served by the organization.

(5) Identifies areas in need of improvement.

(6) Develops a plan to address the areas in need of improvement.

(7) Implements the plan and documents the results.

g. Consumers and their legal representatives have the right to appeal the provider's implementation of the 20 outcomes, or staff or contractual person's action which affects the consumer. The provider shall distribute the policies for consumer appeals and procedures to consumers.

h. The provider shall have written policies and procedures and a staff training program for the identification and reporting of child and dependent adult abuse to the department pursuant to 441—Chapters 175 and 176.

i. The governing body has an active role in the administration of the agency.

j. The governing body receives and uses input from a wide range of local community interests and consumer representation and provides oversight that ensures the provision of high-quality supports and services to consumers.

77.39(2) *Rights and dignity.* Outcome-based standards for rights and dignity are as follows:

a. (Outcome 2) Consumers are valued.

b. (Outcome 3) Consumers live in positive environments.

c. (Outcome 4) Consumers work in positive environments.

d. (Outcome 5) Consumers exercise their rights and responsibilities.

e. (Outcome 6) Consumers have privacy.

f. (Outcome 7) When there is a need, consumers have support to exercise and safeguard their rights.

g. (Outcome 8) Consumers decide which personal information is shared and with whom.

h. (Outcome 9) Consumers make informed choices about where they work.

i. (Outcome 10) Consumers make informed choices on how they spend their free time.

- j. (Outcome 11) Consumers make informed choices about where and with whom they live.
- k. (Outcome 12) Consumers choose their daily routine.
- l. (Outcome 13) Consumers are a part of community life and perform varied social roles.
- m. (Outcome 14) Consumers have a social network and varied relationships.
- n. (Outcome 15) Consumers develop and accomplish personal goals.
- o. (Outcome 16) Management of consumers' money is addressed on an individualized basis.
- p. (Outcome 17) Consumers maintain good health.
- q. (Outcome 18) The consumer's living environment is reasonably safe in the consumer's home and community.
- r. (Outcome 19) The consumer's desire for intimacy is respected and supported.
- s. (Outcome 20) Consumers have an impact on the services they receive.

77.39(3) *The right to appeal.* Consumers and their legal representatives have the right to appeal the provider's application of policies or procedures, or any staff or contractual person's action which affects the consumer. The provider shall distribute the policies for consumer appeals and procedures to consumers.

77.39(4) *Storage and provision of medication.* If the provider stores, handles, prescribes, dispenses or administers prescription or over-the-counter medications, the provider shall develop procedures for the storage, handling, prescribing, dispensing or administration of medication. For controlled substances, procedures shall be in accordance with department of inspections and appeals rule 481—63.18(135).

77.39(5) *Research.* If the provider conducts research involving consumers, the provider shall have written policies and procedures addressing the research. These policies and procedures shall ensure that consumers' rights are protected.

77.39(6) *Incident management and reporting.* As a condition of participation in the medical assistance program, HCBS brain injury waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. **EXCEPTION:** The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, personal emergency response, and transportation.

a. Definitions.

"Major incident" means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph "1," "2," or "3"; or
7. Involves a consumer's location being unknown by provider staff who are assigned protective oversight.

"Minor incident" means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member's

supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

c. Reporting procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member's supervisor.

2. The consumer or the consumer's legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider's service provision. Notification to the guardian, if any, is always required.

3. The consumer's case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department's bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or

2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.

2. The date and time the incident occurred.

3. A description of the incident.

4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.

5. The action that the provider staff took to manage the incident.

6. The resolution of or follow-up to the incident.

7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

77.39(7) *Intake, admission, service coordination, discharge, and referral.*

a. The provider shall have written policies and procedures according to state and federal laws for intake, admission, service coordination, discharge and referral.

b. The provider shall ensure the rights of persons applying for services.

77.39(8) *Certification process.* Reviews of compliance with standards for initial certification and recertification shall be conducted by the department of human services' bureau of long-term care quality assurance staff. Certification carries no assurance that the approved provider will receive funding.

a. Rescinded IAB 9/1/04, effective 11/1/04.

b. Rescinded IAB 9/1/04, effective 11/1/04.

c. Rescinded IAB 9/1/04, effective 11/1/04.

d. The department may request any information from the prospective service provider which is considered pertinent to arriving at a certification decision. This may include, but is not limited to:

(1) Current accreditations, evaluations, inspections and reviews by regulatory and licensing agencies and associations.

(2) Fiscal capacity of the prospective provider to initiate and operate the specified programs on an ongoing basis.

77.39(9) Initial certification. The department shall review the application and accompanying information to see if the provider has the necessary framework to provide services in accordance with all applicable requirements and standards.

a. The department shall make a determination regarding initial certification within 60 days of receipt of the application and notify the provider in writing of the decision unless extended by mutual consent of the parties involved.

b. The decision of the department on initial certification of the providers shall be based on all relevant information, including:

(1) The application for status as an approved provider according to requirements of rules.

(2) A determination of the financial position of the prospective provider in relation to its ability to meet the stated need.

c. Providers applying for initial certification shall be offered technical assistance.

77.39(10) Period of certification. Provider certification shall become effective on the date identified on the certificate of approval and shall terminate in 270 calendar days, one year, or three calendar years from the month of issue. The renewal of certification shall be contingent upon demonstration of continued compliance with certification requirements.

a. Initial certification. Providers eligible for initial certification by the department shall be issued an initial certification for 270 calendar days based on documentation provided.

b. Recertification. After the initial certification, the level of certification shall be based on an on-site review unless the provider has been accredited for similar services by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities (CARF), the Council on Quality and Leadership in Supports for People with Disabilities (The Council), or the Council on Accreditation of Services for Families and Children (COA). The on-site reviews for supported community living and supported employment use interviews with consumers and significant people in the consumer's life to determine whether or not the 20 individual value-based outcomes set forth in subrules 77.39(1) and 77.39(2) and corresponding processes are present for the consumer. Respite services are required to meet Outcome 1 and participate in satisfaction surveys.

Once the outcomes and processes have been determined for all the consumers in the sample, a review team then determines which of the 20 outcomes and processes are present for the provider. A specific outcome is present for the provider when the specific outcome is determined to be present for 75 percent or more of the consumers interviewed. A specific process is present for the provider when the process is determined to be present for 75 percent or more of the consumers interviewed. Since the processes are in the control of the provider and the outcomes are more in the control of the consumer, length of certification will be based more heavily on whether or not the processes are in place to help consumers obtain desired outcomes.

An exit conference shall be held with the organization to share preliminary findings of the certification review. A review report shall be written and sent to the provider within 30 calendar days unless the parties mutually agree to extend that time frame.

Provider certification shall become effective on the date identified on the Certificate of Approval, Form 470-3410, and shall terminate in 270 calendar days, one year, or three calendar years from the month of issue. The renewal of certification shall be contingent upon demonstration of continued compliance with certification requirements.

c. The department may issue four categories of recertification:

(1) *Three-year certification with excellence.* An organization is eligible for certification with excellence if the number of processes present is 18 or higher and the number of outcomes and corresponding processes present together is 12 or higher. Both criteria need to be met to receive three-year certification with excellence. Corrective actions may be required which may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.

(2) *Three-year certification with follow-up monitoring.* An organization is eligible for this type of certification if the number of processes present is 17 or higher and the number of outcomes and corresponding processes present together is 11 or higher. Both criteria need to be met to receive three-year certification. Corrective actions are required which may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.

(3) *One-year certification.* An organization is eligible for this type of certification when the number of processes present is 14 or higher and the number of outcomes and processes present together is 9 or higher. Both criteria need to be met to receive one-year certification. One-year certification may also be given in lieu of longer certification when previously required corrective actions have not been implemented or completed. Corrective actions are required which may be monitored through the assignment of follow-up monitoring either by written report, a plan of corrective actions and improvements, an on-site review, or the provision of technical assistance.

(4) *Probational certification.* A probational certification may be issued to those providers who cannot meet requirements for a one-year certification. This time period shall be granted to the provider to establish and implement corrective actions and improvement activities. During this time period the department may require monitoring of the implementation of the corrective actions through on-site visits, written reports or technical assistance. Probational certification issued for 270 calendar days shall not be renewed or extended and shall require a full on-site follow-up review to be completed. The provider shall be required to achieve at least a one-year certification status at the time of the follow-up review in order to maintain certification.

d. During the course of the review, if a team member encounters a situation that places a consumer in immediate jeopardy, the team member shall immediately notify the provider, the department, and other team members. "Immediate jeopardy" refers to circumstances where the life, health, or safety of a member will be severely jeopardized if the circumstances are not immediately corrected.

(1) The provider shall correct the situation within 24 to 48 hours. If the situation is not corrected within the prescribed time frame, that portion of the provider's services that was the subject of the notification shall not be certified. The department shall immediately discontinue funding for that provider's service.

(2) If this action is appealed and the member, legal guardian, or attorney in fact under a durable power of attorney for health care wants to maintain the provider's services, funding can be reinstated. At that time the provider shall take appropriate action to ensure the life, health, and safety of the members deemed to be at risk as a result of the provider's inaction.

e. As a mandatory reporter, each team member shall be required to follow appropriate procedure in all cases where a condition reportable to child and adult protective services is observed.

f. The department may grant an extension to the period of approval for the following reasons:

(1) A delay in the department's approval decision which is beyond the control of the provider or department.

(2) A request for an extension from a provider to permit the provider to prepare and obtain department approval of corrective actions. The department shall establish the length of extensions on a case-by-case basis.

g. The department may revoke the provider's approval at any time for any of the following reasons:

(1) Findings of a site visit indicate that the provider has failed to implement the corrective actions submitted pursuant to paragraph 77.39(11)"d."

(2) The provider has failed to provide information requested pursuant to paragraph 77.39(11)"e."

(3) The provider refuses to allow the department to conduct a site visit pursuant to paragraph 77.39(11)"f."

(4) There are instances of noncompliance with the standards which were not identified from information submitted on the application.

h. An approved provider shall immediately notify the department, applicable county, or region, the applicable mental health and developmental disabilities planning council, and other interested parties of a decision to withdraw from an HCBS BI waiver service.

i. Following certification, any provider may request technical assistance from the department to bring into conformity those areas found in noncompliance with HCBS requirements. If multiple deficiencies are noted during a review, the department may require that technical assistance be provided to a provider to assist in the implementation of the provider's corrective actions. Providers may be given technical assistance as needed.

j. Appeals. Any adverse action can be appealed by the provider under 441—Chapter 7.

77.39(11) Departmental reviews. Reviews of compliance with standards as indicated in this chapter shall be conducted by the division of mental health and developmental disabilities quality assurance review staff. This review may include on-site case record audits, administrative procedures, clinical practices, and interviews with staff, consumers, and board of directors consistent with the confidentiality safeguards of state and federal laws.

a. Reviews shall be conducted annually with additional reviews conducted at the discretion of the department.

b. Following a departmental review, the department shall submit a copy of the department's determined survey report to the service provider, noting service deficiencies and strengths.

c. The service provider shall develop a plan of corrective action identifying completion time frames for each survey deficiency.

d. The corrective action plan shall be submitted to the Division of Mental Health and Developmental Disabilities, 5th Floor, Hoover State Office Building, Des Moines, Iowa 50319-0114, and include a statement dated and signed, if applicable, by the chief administrative officer and president or chairperson of the governing body that all information submitted to the department is accurate and complete.

e. The department may request the provider to supply subsequent reports on implementation of a corrective action plan submitted pursuant to paragraphs 77.39(11) "c" and "d."

f. The department may conduct a site visit to verify all or part of the information submitted.

77.39(12) Case management service providers. Case management provider organizations are eligible to participate in the Medicaid HCBS brain injury waiver program provided that they meet the standards in 441—Chapter 24 and they are the department of human services, a county or consortium of counties, or a provider under subcontract to the department or a county or consortium of counties.

77.39(13) Supported community living providers.

a. The department shall certify only public or private agencies to provide the supported community living service. The department does not recognize individuals as service providers under the supported community living program.

b. Providers of services meeting the definition of foster care shall also be licensed according to applicable 441—Chapters 108, 112, 114, 115, and 116, which deal with foster care licensing.

c. Providers of service may employ or contract with individuals meeting the definition of foster family homes to provide supported community living services. These individuals shall be licensed according to applicable 441—Chapters 112 and 113, which deal with foster care licensing.

d. The department shall approve living units designed to serve four consumers if the geographic location of the program does not result in an overconcentration of programs in an area.

(1) and (2) Rescinded IAB 8/7/02, effective 10/1/02.

e. The department shall approve living units designed to serve up to four persons except as necessary to prevent an overconcentration of supported community living units in a geographic area.

f. The department shall approve a living unit designed to serve five persons if both of the following conditions are met:

(1) Approval will not result in an overconcentration of supported community living units in a geographic area.

(2) The county in which the living unit is located provides to the bureau of long-term care verification in writing that the approval is needed to address one or more of the following issues:

1. The quantity of services currently available in the county is insufficient to meet the need;
2. The quantity of affordable rental housing in the county is insufficient to meet the need; or
3. Approval will result in a reduction in the size or quantity of larger congregate settings.

77.39(14) *Respite service providers.* Respite providers are eligible to be providers of respite service in the HCBS brain injury waiver if they have documented training or experience with persons with a brain injury.

a. The following agencies may provide respite services:

- (1) Respite providers certified under the HCBS intellectual disability waiver.
- (2) Adult day care providers that meet the conditions of participation set forth in subrule 77.39(20).
- (3) Group living foster care facilities for children licensed by the department according to 441—Chapters 112 and 114 to 116 and child care centers licensed according to 441—Chapter 109.
- (4) Camps certified by the American Camping Association.
- (5) Home care agencies that meet the conditions of participation set forth in subrule 77.30(1).
- (6) Nursing facilities, intermediate care facilities for the mentally retarded, and hospitals enrolled as providers in the Iowa Medicaid program.
- (7) Residential care facilities for persons with mental retardation licensed by the department of inspections and appeals.
- (8) Home health agencies that are certified to participate in the Medicare program.
- (9) Agencies certified by the department to provide respite services in the consumer's home that meet the requirements of subrules 77.39(1) and 77.39(3) through 77.39(7).
- (10) Assisted living programs certified by the department of inspections and appeals.

b. Respite providers shall meet the following conditions:

- (1) Providers shall maintain the following information that shall be updated at least annually:
 1. The consumer's name, birth date, age, and address and the telephone number of each parent, guardian or primary caregiver.
 2. An emergency medical care release.
 3. Emergency contact telephone numbers such as the number of the consumer's physician and the parents, guardian, or primary caregiver.
 4. The consumer's medical issues, including allergies.
 5. The consumer's daily schedule which includes the consumer's preferences in activities or foods or any other special concerns.
- (2) Procedures shall be developed for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications administered. Home health agencies must follow Medicare regulations for medication dispensing.

All medications shall be stored in their original containers, with the accompanying physician's or pharmacist's directions and label intact. Medications shall be stored so they are inaccessible to consumers and the public. Nonprescription medications shall be labeled with the consumer's name.

In the case of medications that are administered on an ongoing, long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription.

(3) Policies shall be developed for:

1. Notifying the parent, guardian or primary caregiver of any injuries or illnesses that occur during respite provision. A parent's, guardian's or primary caregiver's signature is required to verify receipt of notification.
2. Requiring the parent, guardian or primary caregiver to notify the respite provider of any injuries or illnesses that occurred prior to respite provision.
3. Documenting activities and times of respite. This documentation shall be made available to the parent, guardian or primary caregiver upon request.
4. Ensuring the safety and privacy of the individual. Policies shall at a minimum address threat of fire, tornado, or flood and bomb threats.

c. A facility providing respite under this subrule shall not exceed the facility's licensed capacity, and services shall be provided in locations consistent with licensure.

d. Respite provided outside the consumer's home or the facility covered by the licensure, certification, accreditation, or contract must be approved by the parent, guardian or primary caregiver and the interdisciplinary team and must be consistent with the way the location is used by the general public. Respite in these locations shall not exceed 72 continuous hours.

77.39(15) *Supported employment providers.*

a. The following agencies may provide supported employment services:

(1) An agency that is accredited by the Commission on Accreditation of Rehabilitation Facilities as an organizational employment service provider, a community employment service provider or a provider of a similar service.

(2) An agency that is accredited by the Council on Accreditation of Services for Families and Children for similar services.

(3) An agency that is accredited by the Joint Commission on Accreditation of Healthcare Organizations for similar services.

(4) An agency that is accredited by the Council on Quality and Leadership in Supports for People with Disabilities for similar services.

(5) An agency that is accredited by the International Center for Clubhouse Development.

b. Providers responsible for the payroll of members shall have policies that ensure compliance with state and federal labor laws and regulations, which include, but are not limited to:

(1) Member vacation, sick leave and holiday compensation.

(2) Procedures for payment schedules and pay scale.

(3) Procedures for provision of workers' compensation insurance.

(4) Procedures for the determination and review of commensurate wages.

c. The department will contract only with public or private agencies to provide supported employment services. The department does not recognize individuals as service providers under the supported employment program.

77.39(16) *Home and vehicle modification providers.* The following providers may provide home and vehicle modification:

a. Providers eligible to participate as home and vehicle modification providers under the elderly or health and disability waiver, enrolled as home and vehicle modification providers under the physical disability waiver, or certified as home and vehicle modification providers under the physical disability waiver.

b. Community businesses that have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations and that submit verification of current liability and workers' compensation insurance.

77.39(17) *Personal emergency response system providers.* Personal emergency response system providers shall be agencies which meet the conditions of participation set forth in subrule 77.33(2).

a. Providers shall be certified annually.

b. The service provider shall submit documentation to the department supporting continued compliance with the requirements set forth in subrule 77.33(2) 90 days before the expiration of the current certification.

77.39(18) *Transportation service providers.* This service is not to be provided at the same time as supported community service, which includes transportation. The following providers may provide transportation:

a. Area agencies on aging as designated in rule 17—4.4(231) or with letters of approval from the area agencies on aging stating the organization is qualified to provide transportation services.

b. Community action agencies as designated in Iowa Code section 216A.93.

c. Regional transit agencies as recognized by the Iowa department of transportation.

d. Providers with purchase of service contracts to provide transportation pursuant to 441—Chapter 150.

e. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

f. Transportation providers contracting with the nonemergency medical transportation contractor.

77.39(19) *Specialized medical equipment providers.* The following providers may provide specialized medical equipment:

a. Medical equipment and supply dealers participating as providers in the Medicaid program.

b. Retail and wholesale businesses participating as providers in the Medicaid program which provide specialized medical equipment as defined in 441—subrule 78.43(8).

77.39(20) *Adult day care providers.* Adult day care providers shall be agencies that are certified by the department of inspections and appeals as being in compliance with the standards for adult day services programs at 481—Chapter 70.

77.39(21) *Family counseling and training providers.* Family counseling and training providers shall be one of the following:

a. Providers certified under the community mental health center standards established by the mental health and developmental disabilities commission, set forth in 441—Chapter 24, Divisions I and III, and that employ staff to provide family counseling and training who meet the definition of qualified brain injury professional as set forth in rule 441—83.81(249A).

b. Providers licensed as meeting the hospice standards and requirements set forth in department of inspections and appeals rules in 481—Chapter 53 or certified to meet the standards under the Medicare program for hospice programs, and that employ staff who meet the definition of qualified brain injury professional as set forth in rule 441—83.81(249A).

c. Providers accredited under the mental health service provider standards established by the mental health and developmental and disabilities commission, set forth in 441—Chapter 24, Divisions I and IV, and that employ staff to provide family counseling and training who meet the definition of qualified brain injury professional as set forth in rule 441—83.81(249A).

d. Individuals who meet the definition of qualified brain injury professional as set forth in rule 441—83.81(249A).

e. Agencies certified as brain injury waiver providers pursuant to rule 441—77.39(249A) that employ staff to provide family counseling who meet the definition of a qualified brain injury professional as set forth in rule 441—83.81(249A).

77.39(22) *Prevocational services providers.* Providers of prevocational services must meet the Commission on Accreditation of Rehabilitation Facilities standards for work adjustment service providers.

77.39(23) *Behavioral programming providers.* Behavioral programming providers shall be required to have experience with or training regarding the special needs of persons with a brain injury. In addition, they must meet the following requirements.

a. Behavior assessment, and development of an appropriate intervention plan, and periodic reassessment of the plan, and training of staff who shall implement the plan must be done by a qualified brain injury professional as defined in rule 441—83.81(249A). Formal assessment of the consumers' intellectual and behavioral functioning must be done by a licensed psychologist or a psychiatrist who is certified by the American Board of Psychiatry.

b. Implementation of the plan and training and supervision of caregivers, including family members, must be done by behavioral aides who have been trained by a qualified brain injury professional as defined in rule 441—83.81(249A) and who are employees of one of the following:

(1) Agencies which are certified under the community mental health center standards established by the mental health and developmental disabilities commission, set forth in 441—Chapter 24, Divisions I and III.

(2) Agencies which are licensed as meeting the hospice standards and requirements set forth in department of inspections and appeals rules 481—Chapter 53 or which are certified to meet the standards under the Medicare program for hospice programs.

(3) Agencies which are accredited under the mental health service provider standards established by the mental health and disabilities commission, set forth in 441—Chapter 24, Divisions I and IV.

(4) Home health aide providers meeting the standards set forth in subrule 77.33(3). Home health aide providers certified by Medicare shall be considered to have met these standards.

(5) Brain injury waiver providers certified pursuant to rule 441—77.39(249A).

77.39(24) *Consumer-directed attendant care providers.* The following providers may provide consumer-directed attendant care service:

a. An individual who contracts with the member to provide attendant care service and who is:

(1) At least 18 years of age.

(2) Qualified by training or experience to carry out the member's plan of care pursuant to the department-approved case plan or individual comprehensive plan.

(3) Not the spouse of the member or a parent or stepparent of a member aged 17 or under.

(4) Not the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

b. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

c. Home health agencies which are certified to participate in the Medicare program.

d. Chore providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating that the organization is qualified to provide chore services.

e. Community action agencies as designated in Iowa Code section 216A.93.

f. Providers certified under an HCBS waiver for supported community living.

g. Assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.

h. Adult day service providers that are certified by the department of inspections and appeals under 481—Chapter 70.

77.39(25) *Interim medical monitoring and treatment providers.*

a. The following providers may provide interim medical monitoring and treatment services:

(1) Home health agencies certified to participate in the Medicare program.

(2) Supported community living providers certified according to subrule 77.37(14) or 77.39(13).

b. Staff requirements. Staff members providing interim medical monitoring and treatment services to members shall meet all of the following requirements:

(1) Be at least 18 years of age.

(2) Not be the spouse of the member or a parent or stepparent of the member if the member is aged 17 or under.

(3) Not be a usual caregiver of the member.

(4) Be qualified by training or experience to provide medical intervention or intervention in a medical emergency necessary to carry out the member's plan of care. The training or experience required must be determined by the member's usual caregivers and a licensed medical professional on the member's interdisciplinary team and must be documented in the member's service plan.

c. Service documentation. Providers shall maintain clinical and fiscal records necessary to fully disclose the extent of services furnished to members. Records shall specify by service date the procedures performed, together with information concerning progress of treatment.

77.39(26) *Financial management service.* Consumers who elect the consumer choices option shall work with a financial institution that meets the qualifications in subrule 77.30(13).

77.39(27) *Independent support brokerage.* Consumers who elect the consumer choices option shall work with an independent support broker who meets the qualifications in subrule 77.30(14).

77.39(28) *Self-directed personal care.* Consumers who elect the consumer choices option may choose to purchase self-directed personal care services from an individual or business that meets the requirements in subrule 77.30(15).

77.39(29) *Individual-directed goods and services.* Consumers who elect the consumer choices option may choose to purchase individual-directed goods and services from an individual or business that meets the requirements in subrule 77.30(16).

77.39(30) *Self-directed community supports and employment.* Consumers who elect the consumer choices option may choose to purchase self-directed community supports and employment from an individual or business that meets the requirements in subrule 77.30(17).

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 0191C, IAB 7/11/12, effective 7/1/12; ARC 0359C, IAB 10/3/12, effective 12/1/12; ARC 0757C, IAB 5/29/13, effective 8/1/13; ARC 1071C, IAB 10/2/13, effective 10/1/13; ARC 1149C, IAB 10/30/13, effective 1/1/14; ARC 1445C, IAB 4/30/14, effective 7/1/14; ARC 1638C, IAB 10/1/14, effective 11/5/14]

441—77.40(249A) Lead inspection agencies. The Iowa department of public health and agencies certified by the Iowa department of public health pursuant to 641—subrule 70.5(5) are eligible to participate in the Medicaid program as providers of lead inspection services.

This rule is intended to implement Iowa Code section 249A.4.

441—77.41(249A) HCBS physical disability waiver service providers. Providers shall be eligible to participate in the Medicaid physical disability waiver program if they meet the requirements in this rule and the subrules applicable to the individual service. Enrolled providers shall maintain the certification listed in the applicable subrules in order to remain eligible providers.

Services shall be rendered by a person who is at least 16 years old (except as otherwise provided in this rule) and is not the spouse of the consumer served or the parent or stepparent of a consumer aged 17 or under. People who are 16 or 17 years old must be employed and supervised by an enrolled HCBS provider unless they are employed to provide self-directed personal care services through the consumer choices option. A person hired for self-directed personal care services need not be supervised by an enrolled HCBS provider. A person hired through the consumer choices option for independent support brokerage, self-directed personal care, individual-directed goods and services, or self-directed community support and employment is not required to enroll as a Medicaid provider and is not subject to the requirements of subrule 77.41(1).

77.41(1) Enrollment process. Reviews of compliance with standards for initial enrollment shall be conducted by the department's quality assurance staff. Enrollment carries no assurance that the approved provider will receive funding.

Review of a provider may occur at any time.

The department may request any information from the prospective service provider that is pertinent to arriving at an enrollment decision. This may include, but is not limited to:

- a. Current accreditations, evaluations, inspection reports, and reviews by regulatory and licensing agencies and associations.
- b. Fiscal capacity of the prospective provider to initiate and operate the specified programs on an ongoing basis.

77.41(2) Consumer-directed attendant care providers. The following providers may provide consumer-directed attendant care service:

- a. An individual who contracts with the member to provide consumer-directed attendant care and who is:

- (1) At least 18 years of age.
- (2) Qualified by training or experience to carry out the member's plan of care pursuant to the department-approved case plan or individual comprehensive plan.
- (3) Not the spouse or guardian of the member or a parent or stepparent of a member aged 17 or under.
- (4) Not the recipient of respite services paid through home- and community-based services on behalf of a member who receives home- and community-based services.

- b. Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

- c. Home health agencies that are certified to participate in the Medicare program.
- d. Chore providers subcontracting with area agencies on aging or with letters of approval from the area agencies on aging stating that the organization is qualified to provide chore services.
- e. Community action agencies as designated in Iowa Code section 216A.103.
- f. Providers certified under an HCBS waiver for supported community living.
- g. Assisted living programs that are certified by the department of inspections and appeals under 481—Chapter 69.
- h. Adult day service providers that are certified by the department of inspections and appeals under 481—Chapter 70.

77.41(3) *Home and vehicle modification providers.* The following providers may provide home and vehicle modifications:

a. Providers eligible to participate as home and vehicle modification providers under the elderly or health and disability waiver or certified as home and vehicle modification providers under the home- and community-based services intellectual disability or brain injury waiver.

b. Community businesses that have all necessary licenses and permits to operate in conformity with federal, state, and local laws and regulations and that submit verification of current liability and workers' compensation insurance.

77.41(4) *Personal emergency response system providers.* Personal emergency response system providers shall be agencies which meet the conditions of participation set forth in subrule 77.33(2).

77.41(5) *Specialized medical equipment providers.* The following providers may provide specialized medical equipment:

a. Medical equipment and supply dealers participating as providers in the Medicaid program.

b. Retail and wholesale businesses participating as providers in the Medicaid program which provide specialized medical equipment as defined in 441—subrule 78.46(4).

77.41(6) *Transportation service providers.* The following providers may provide transportation:

a. Area agencies on aging as designated in 17—4.4(231) or with letters of approval from the area agencies on aging stating the organization is qualified to provide transportation services.

b. Community action agencies as designated in Iowa Code section 216A.93.

c. Regional transit agencies as recognized by the Iowa department of transportation.

d. Nursing facilities licensed pursuant to Iowa Code chapter 135C.

e. Transportation providers contracting with the nonemergency medical transportation contractor.

77.41(7) *Financial management service.* Consumers who elect the consumer choices option shall work with a financial institution that meets the qualifications in subrule 77.30(13).

77.41(8) *Independent support brokerage.* Consumers who elect the consumer choices option shall work with an independent support broker who meets the qualifications in subrule 77.30(14).

77.41(9) *Self-directed personal care.* Consumers who elect the consumer choices option may choose to purchase self-directed personal care services from an individual or business that meets the requirements in subrule 77.30(15).

77.41(10) *Individual-directed goods and services.* Consumers who elect the consumer choices option may choose to purchase individual-directed goods and services from an individual or business that meets the requirements in subrule 77.30(16).

77.41(11) *Self-directed community supports and employment.* Consumers who elect the consumer choices option may choose to purchase self-directed community supports and employment from an individual or business that meets the subrule requirements in 77.30(17).

77.41(12) *Incident management and reporting.* As a condition of participation in the medical assistance program, HCBS physical disability waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and with the incident management and reporting requirements in this subrule. EXCEPTION: The conditions in this subrule do not apply to providers of goods and services purchased under the consumer choices option or providers of home and vehicle modification, specialized medical equipment, personal emergency response, and transportation.

a. Definitions.

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician's treatment or admission to a hospital;

2. Results in the death of any person;

3. Requires emergency mental health treatment for the consumer;

4. Requires the intervention of law enforcement;

5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;

6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or

7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“*Minor incident*” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

b. *Reporting procedure for minor incidents.* Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

c. *Reporting procedure for major incidents.* When a major incident occurs or a staff member becomes aware of a major incident:

(1) The staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(2) By the end of the next calendar day after the incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(3) The following information shall be reported:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.
7. The date the report is made and the handwritten or electronic signature of the person making the report.

(4) Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about the incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

d. Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

This rule is intended to implement Iowa Code section 249A.4.

[ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 0191C, IAB 7/11/12, effective 7/1/12; ARC 0359C, IAB 10/3/12, effective 12/1/12; ARC 0757C, IAB 5/29/13, effective 8/1/13; ARC 1071C, IAB 10/2/13, effective 10/1/13]

441—77.42(249A) Public health agencies. Public health agencies are eligible to participate in the medical assistance program when they serve as a public health entity within the local board of health jurisdiction pursuant to 641—subrule 77.3(3).

This rule is intended to implement Iowa Code section 249A.4.

[ARC 0358C, IAB 10/3/12, effective 11/7/12]

441—77.43(249A) Infant and toddler program providers. An agency is eligible to participate in the medical assistance program as a provider of infant and toddler program services under rule 441—78.49(249A) if the agency:

1. Is in good standing under the infants and toddlers with disabilities program administered by the department of education, the department of public health, the department of human services, and the Iowa Child Health Specialty Clinics pursuant to the interagency agreement between these agencies under Subchapter III of the federal Individuals with Disabilities Education Act (IDEA); and

2. Meets the following additional requirements.

77.43(1) Licensure. Covered services shall be provided by personnel who are licensed, endorsed, registered, recognized, or qualified as provided in this subrule and shall be within the scope of the applicable license, endorsement, registration, recognition, or qualification.

a. Personnel providing audiological or speech-language services shall be licensed by the Iowa board of speech pathology and audiology as a speech pathologist or audiologist pursuant to 645—Chapters 299, 300 and 303 through 305.

b. Personnel providing physical therapy shall be licensed by the Iowa board of physical and occupational therapy as a physical therapist pursuant to 645—Chapters 199 through 204.

c. Personnel providing occupational therapy shall be licensed by the Iowa board of physical and occupational therapy as an occupational therapist pursuant to 645—Chapters 205 through 210.

d. Personnel providing psychological evaluations and counseling or psychotherapy services shall be:

(1) Endorsed by the Iowa board of educational examiners as a school psychologist pursuant to rule 282—15.11(272);

(2) Licensed by the Iowa board of psychology as a psychologist pursuant to 645—Chapters 239 through 243;

(3) Licensed by the Iowa board of social work as a social worker pursuant to 645—Chapters 279 through 284;

(4) Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11; or

(5) Registered by the Iowa nursing board as an advanced registered nurse practitioner pursuant to 655—Chapter 7.

e. Personnel providing nursing services shall be licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6.

f. Personnel providing vision services shall be:

(1) Licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6;

(2) Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11; or

(3) Licensed by the Iowa board of optometry as an optometrist pursuant to 645—Chapter 180.

g. Developmental services shall be provided by personnel who meet standards established pursuant to department of education rule 281—120.19(34CFR303).

- h.* Medical transportation shall be provided by licensed drivers.
- i.* Other services shall be provided by staff who are:
 - (1) Recognized as a special education paraprofessional pursuant to department of education rule 281—41.403(256B);
 - (2) Endorsed by the Iowa board of educational examiners as a school psychologist pursuant to rule 282—15.11(272);
 - (3) Endorsed by the Iowa board of educational examiners as a speech-language pathologist pursuant to rule 282—15.12(272);
 - (4) Endorsed by the Iowa board of educational examiners as an orientation and mobility specialist pursuant to rule 282—15.15(272);
 - (5) Endorsed by the Iowa board of educational examiners as a school occupational therapist pursuant to rule 282—15.16(272);
 - (6) Endorsed by the Iowa board of educational examiners as a school physical therapist pursuant to rule 282—15.17(272);
 - (7) Endorsed by the Iowa board of educational examiners as a special education nurse pursuant to rule 282—15.18(272);
 - (8) Endorsed by the Iowa board of educational examiners as a school social worker pursuant to rule 282—15.19(272);
 - (9) Licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6; or
 - (10) Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11.

77.43(2) Documentation requirements. As a condition of participation, the provider shall be responsible for maintaining accurate and current documentation of services provided in the child's record. Documentation of all services performed is required and must include:

- a.* Date, time, location, and description of each service provided and identification of the individual rendering the service by name and professional or paraprofessional designation.
- b.* An assessment and response to interventions and services.
- c.* An individual family service plan (IFSP) including all changes and revisions, as developed by the service coordinator pursuant to rule 281—41.5(256B,34CFR300).
- d.* Documentation of progress toward achieving the child's or family's action steps and outcomes as identified in the individual family service plan (IFSP).

This rule is intended to implement Iowa Code section 249A.4.

441—77.44(249A) Local education agency services providers. School districts accredited by the department of education pursuant to 281—Chapter 12, the Iowa Braille and Sight Saving School governed by the state board of regents pursuant to Iowa Code section 262.7(4), and the State School for the Deaf governed by the state board of regents pursuant to Iowa Code section 262.7(5) are eligible to participate in the medical assistance program as providers of local education agency (LEA) services under rule 441—78.50(249A) if the following conditions are met.

77.44(1) Licensure. Covered services shall be provided by personnel who are licensed, endorsed, registered, recognized, or qualified as provided in this subrule and shall be within the scope of the applicable license, endorsement, registration, recognition, or qualification.

- a.* Personnel providing audiological or speech-language services shall be licensed by the Iowa board of speech pathology and audiology as a speech pathologist or audiologist pursuant to 645—Chapters 299, 300 and 303 through 305.

- b.* Personnel providing physical therapy shall be licensed by the Iowa board of physical and occupational therapy as a physical therapist pursuant to 645—Chapters 199 through 204.

- c.* Personnel providing occupational therapy shall be licensed by the Iowa board of physical and occupational therapy as an occupational therapist pursuant to 645—Chapters 205 through 210.

- d.* Personnel providing psychological evaluations and counseling or psychotherapy services shall be:

- (1) Endorsed by the Iowa board of educational examiners as a school psychologist pursuant to rule 282—15.11(272);
 - (2) Licensed by the Iowa board of psychology as a psychologist pursuant to 645—Chapters 239 through 243;
 - (3) Licensed by the Iowa board of social work as a social worker pursuant to 645—Chapters 279 through 284;
 - (4) Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11; or
 - (5) Registered by the Iowa nursing board as an advanced registered nurse practitioner pursuant to 655—Chapter 7.
- e.* Personnel providing nursing services shall be licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6.
 - f.* Personnel providing vision services shall be:
 - (1) Licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6;
 - (2) Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11; or
 - (3) Licensed by the Iowa board of optometry as an optometrist pursuant to 645—Chapter 180.
 - g.* Developmental services shall be provided by personnel who meet standards established pursuant to department of education rule 281—120.19(34CFR303).
 - h.* Medical transportation shall be provided by licensed drivers.
 - i.* Other services shall be provided by staff who are:
 - (1) Recognized as a special education paraprofessional pursuant to department of education rule 281—41.403(256B);
 - (2) Endorsed by the Iowa board of educational examiners as a school psychologist pursuant to rule 282—15.11(272);
 - (3) Endorsed by the Iowa board of educational examiners as a speech-language pathologist pursuant to rule 282—15.12(272);
 - (4) Endorsed by the Iowa board of educational examiners as an orientation and mobility specialist pursuant to rule 282—15.15(272);
 - (5) Endorsed by the Iowa board of educational examiners as a school occupational therapist pursuant to rule 282—15.16(272);
 - (6) Endorsed by the Iowa board of educational examiners as a school physical therapist pursuant to rule 282—15.17(272);
 - (7) Endorsed by the Iowa board of educational examiners as a special education nurse pursuant to rule 282—15.18(272);
 - (8) Endorsed by the Iowa board of educational examiners as a school social worker pursuant to rule 282—15.19(272);
 - (9) Licensed by the Iowa nursing board as a registered or licensed practical nurse pursuant to 655—Chapters 3 through 6; or
 - (10) Licensed by the Iowa board of medicine as a physician pursuant to 653—Chapters 9 through 11.

77.44(2) Documentation requirements. As a condition of participation, the provider shall be responsible for maintaining accurate and current documentation in the child's record. Documentation of all services performed is required and must include:

- a.* Date, time, duration, location, and description of each service delivered and identification of the individual rendering the service by name and professional or paraprofessional designation.
- b.* An assessment and response to interventions and services.
- c.* Progress toward goals in the individual education plan (IEP) or individual health plan (IHP) pursuant to 281—Chapter 41, Division VIII, or 281—subrule 41.96(1).

This rule is intended to implement Iowa Code section 249A.4.

441—77.45(249A) Indian health service 638 facilities. A health care facility owned and operated by American Indian or Alaskan native tribes or tribal organizations with funding authorized by Title I or Title III of the Indian Self-Determination and Education Assistance Act (P.L. 93-638) is eligible to participate in the medical assistance program if the following conditions are met:

77.45(1) Licensure. Services must be rendered by practitioners who meet applicable professional licensure requirements.

77.45(2) Documentation. Medical records must be maintained at the same standards as are required for the applicable licensed medical practitioner.

This rule is intended to implement Iowa Code section 249A.4.

441—77.46(249A) HCBS children's mental health waiver service providers. HCBS children's mental health waiver services shall be rendered by provider agencies that meet the general provider standards in subrule 77.46(1) and also meet the standards in subrules 77.46(2) to 77.46(5) that are specific to the waiver services provided. A provider that is approved for the same service under another HCBS Medicaid waiver shall be eligible to enroll for that service under the children's mental health waiver.

77.46(1) General provider standards. All providers of HCBS children's mental health waiver services shall meet the following standards:

a. Fiscal capacity. Providers must demonstrate the fiscal capacity to provide services on an ongoing basis.

b. Direct care staff.

(1) Direct care staff must be at least 18 years of age.

(2) Providers must complete child abuse, dependent adult abuse, and criminal background screenings pursuant to Iowa Code section 249A.29 before employment of a staff member who will provide direct care.

(3) Direct care staff may not be the spouse of the consumer or the parent or stepparent of the consumer.

c. Outcome-based standards and quality assurance.

(1) Providers shall implement the following outcome-based standards for the rights and dignity of children with serious emotional disturbance:

1. Consumers are valued.

2. Consumers are a part of community life.

3. Consumers develop meaningful goals.

4. Consumers maintain physical and mental health.

5. Consumers are safe.

6. Consumers and their families have an impact on the services received.

(2) The department's quality assurance staff shall conduct random quality assurance reviews to assess the degree to which the outcome-based standards have been implemented in service provision. Results of outcome-based quality assurance reviews shall be forwarded to the certifying or accrediting entity.

(3) A quality assurance review shall include interviews with the consumer and the consumer's parents or legal guardian, with informed consent, and interviews with designated targeted case managers.

(4) A quality assurance review may include interviews with provider staff, review of case files, review of staff training records, review of compliance with the general provider standards in this subrule, and review of other organizational policies and procedures and documentation.

(5) Corrective action shall be required if the quality assurance review demonstrates that service provision or provider policies and procedures do not reflect the outcome-based standards. Technical assistance for corrective action shall be available from the department's quality assurance staff.

d. Incident management and reporting. As a condition of participation in the medical assistance program, HCBS children's mental health waiver service providers must comply with the requirements of Iowa Code sections 232.69 and 235B.3 regarding the reporting of child abuse and dependent adult abuse and must comply with the following incident management and reporting requirements. EXCEPTION:

The conditions in this paragraph do not apply to providers of environmental modifications and adaptive devices.

(1) Definitions.

“Major incident” means an occurrence involving a consumer during service provision that:

1. Results in a physical injury to or by the consumer that requires a physician’s treatment or admission to a hospital;
2. Results in the death of any person;
3. Requires emergency mental health treatment for the consumer;
4. Requires the intervention of law enforcement;
5. Requires a report of child abuse pursuant to Iowa Code section 232.69 or a report of dependent adult abuse pursuant to Iowa Code section 235B.3;
6. Constitutes a prescription medication error or a pattern of medication errors that leads to the outcome in paragraph “1,” “2,” or “3”; or
7. Involves a consumer’s location being unknown by provider staff who are assigned protective oversight.

“Minor incident” means an occurrence involving a consumer during service provision that is not a major incident and that:

1. Results in the application of basic first aid;
2. Results in bruising;
3. Results in seizure activity;
4. Results in injury to self, to others, or to property; or
5. Constitutes a prescription medication error.

(2) Reporting procedure for minor incidents. Minor incidents may be reported in any format designated by the provider. When a minor incident occurs or a staff member becomes aware of a minor incident, the staff member involved shall submit the completed incident report to the staff member’s supervisor within 72 hours of the incident. The completed report shall be maintained in a centralized file with a notation in the consumer’s file.

(3) Notification procedure for major incidents. When a major incident occurs or a staff member becomes aware of a major incident, the staff member involved shall notify the following persons of the incident by the end of the next calendar day after the incident:

1. The staff member’s supervisor.
2. The consumer or the consumer’s legal guardian. EXCEPTION: Notification to the consumer is required only if the incident took place outside of the provider’s service provision. Notification to the guardian, if any, is always required.
3. The consumer’s case manager.

(4) Reporting procedure for major incidents. By the end of the next calendar day after a major incident, the staff member who observed or first became aware of the incident shall also report as much information as is known about the incident to the department’s bureau of long-term care either:

1. By direct data entry into the Iowa Medicaid Provider Access System, or
2. By faxing or mailing Form 470-4698, Critical Incident Report, according to the directions on the form.

(5) Information to be reported. The following information shall be reported about a major incident:

1. The name of the consumer involved.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all provider staff and others who were present at the time of the incident or who responded after becoming aware of the incident. The confidentiality of other waiver-eligible or non-waiver-eligible consumers who were present must be maintained by the use of initials or other means.
5. The action that the provider staff took to manage the incident.
6. The resolution of or follow-up to the incident.

7. The date the report is made and the handwritten or electronic signature of the person making the report.

(6) Response to report. Submission of the initial report will generate a workflow in the Individualized Services Information System (ISIS) for follow-up by the case manager. When complete information about a major incident is not available at the time of the initial report, the provider must submit follow-up reports until the case manager is satisfied with the incident resolution and follow-up. The completed report shall be maintained in a centralized file with a notation in the consumer's file.

(7) Tracking and analysis. The provider shall track incident data and analyze trends to assess the health and safety of consumers served and determine if changes need to be made for service implementation or if staff training is needed to reduce the number or severity of incidents.

77.46(2) *Environmental modifications, adaptive devices, and therapeutic resources providers.* The following agencies may provide environmental modifications, adaptive devices, and therapeutic resources under the children's mental health waiver:

a. A community business that:

(1) Possesses all necessary licenses and permits to operate in conformity with federal, state, and local statutes and regulations, including Iowa Code chapter 490; and

(2) Submits verification of current liability and workers' compensation insurance.

b. A retail or wholesale business that otherwise participates as a provider in the Medicaid program.

c. A home and vehicle modification provider enrolled under another HCBS Medicaid waiver.

d. A provider enrolled under the HCBS home- and community-based services intellectual disability or brain injury waiver as a supported community living provider.

e. A provider enrolled under the HCBS children's mental health waiver as a family and community support services provider.

77.46(3) *Family and community support services providers.*

a. *Qualified providers.* The following agencies may provide family and community support services under the children's mental health waiver:

(1) Behavioral health intervention providers qualified under 441—77.12(249A).

(2) Community mental health centers accredited in good standing as providers of outpatient psychotherapy and counseling under 441—Chapter 24.

b. *Staff training.* The agency shall meet the following training requirements as a condition of providing family and community support services under the children's mental health waiver:

(1) Within one month of employment, staff members must receive the following training:

1. Orientation regarding the agency's mission, policies, and procedures; and

2. Orientation regarding HCBS philosophy and outcomes for rights and dignity found in 77.36(1)“c” for the children's mental health waiver.

(2) Within four months of employment, staff members must receive training regarding the following:

1. Serious emotional disturbance in children and provision of services to children with serious emotional disturbance;

2. Confidentiality;

3. Provision of medication according to agency policy and procedure;

4. Identification and reporting of child abuse;

5. Incident reporting;

6. Documentation of service provision;

7. Appropriate behavioral interventions; and

8. Professional ethics.

(3) Until a staff member receives the training identified in subparagraphs (1) and (2), the staff member shall not provide any direct service without the presence of experienced staff.

(4) Within the first year of employment, staff members must complete 24 hours of training in children's mental health issues.

(5) During each consecutive year of employment, staff members must complete 12 hours of training in children's mental health issues.

c. Support of crisis intervention plan. As a condition of providing services under the children's mental health waiver, a family and community support provider shall develop and implement policies and procedures for maintaining the integrity of the individualized crisis intervention plan as defined in 441—24.1(225C) that is developed by each consumer's interdisciplinary team. The policies and procedures shall address:

- (1) Sharing with the case manager and the interdisciplinary team information pertinent to the development of the consumer's crisis intervention plan.
- (2) Training staff before service provision, in cooperation with the consumer's parents or legal guardian, regarding the consumer's individual mental health needs and individualized supports as identified in the crisis intervention plan.
- (3) Ensuring that all staff have access to a written copy of the most current crisis intervention plan during service provision.
- (4) Ensuring that the plan contains current and accurate information by updating the case manager within 24 hours regarding any circumstance or issue that would have an impact on the consumer's mental health or change the consumer's crisis intervention plan.

d. Intake, admission, and discharge. As a condition of providing services under the children's mental health waiver, a family and community support provider shall have written policies and procedures for intake, admission, and discharge.

77.46(4) In-home family therapy providers.

a. Qualified providers. The following agencies may provide in-home family therapy under the children's mental health waiver:

- (1) Community mental health centers accredited in good standing as providers of outpatient psychotherapy and counseling under 441—Chapter 24.
- (2) Mental health professionals licensed pursuant to 645—Chapter 31, 240, or 280 or possessing an equivalent license in another state.

b. Staff training. The agency shall meet the following training requirements as a condition of providing in-home family therapy under the children's mental health waiver:

- (1) Within one month of employment, staff members must receive the following training:
 1. Orientation regarding the agency's mission, policies, and procedures; and
 2. Orientation regarding HCBS philosophy and outcomes for rights and dignity found in 77.46(1) "c" for the children's mental health waiver.
- (2) Within four months of employment, staff members must receive training regarding the following:
 1. Serious emotional disturbance in children and service provision to children with serious emotional disturbance;
 2. Confidentiality;
 3. Provision of medication according to agency policy and procedure;
 4. Identification and reporting of child abuse;
 5. Incident reporting;
 6. Documentation of service provision;
 7. Appropriate behavioral interventions; and
 8. Professional ethics.
- (3) Until a staff member receives the training identified in subparagraphs (1) and (2), the staff member shall not provide any direct service without the presence of experienced staff.
- (4) Within the first year of employment, staff members must complete 24 hours of training in children's mental health issues.
- (5) During each consecutive year of employment, staff members must complete 12 hours of training in children's mental health issues.

c. Support of crisis intervention plan. As a condition of providing services under the children's mental health waiver, an in-home family therapy provider shall develop and implement policies and procedures for maintaining the integrity of the individualized crisis intervention plan as defined in

441—24.1(225C) that is developed by each consumer's interdisciplinary team. The policies and procedures shall address:

(1) Sharing with the case manager and the interdisciplinary team information pertinent to the development of the consumer's crisis intervention plan.

(2) Training staff before service provision, in cooperation with the consumer's parents or legal guardian, regarding the consumer's individual mental health needs and individualized supports as identified in the crisis intervention plan.

(3) Ensuring that all staff have access to a written copy of the most current crisis intervention plan during service provision.

(4) Ensuring that the plan contains current and accurate information by updating the case manager within 24 hours regarding any circumstance or issue that would have an impact on the consumer's mental health or change the consumer's crisis intervention plan.

d. Intake, admission, and discharge. As a condition of providing services under the children's mental health waiver, an in-home family therapy provider shall have written policies and procedures for intake, admission, and discharge.

77.46(5) Respite care providers.

a. Qualified providers. The following agencies may provide respite services under the children's mental health waiver:

(1) Providers certified or enrolled as respite providers under another Medicaid HCBS waiver.

(2) Group living foster care facilities for children licensed in good standing by the department according to 441—Chapters 112 and 114 to 116.

(3) Camps certified in good standing by the American Camping Association.

(4) Home health agencies that are certified in good standing to participate in the Medicare program.

(5) Agencies authorized to provide similar services through a contract with the department of public health (IDPH) for local public health services. The agency must provide a current IDPH local public health services contract number.

(6) Adult day care providers that are certified in good standing by the department of inspections and appeals as being in compliance with the standards for adult day services programs at 481—Chapter 70.

(7) Assisted living programs certified in good standing by the department of inspections and appeals.

(8) Residential care facilities for persons with mental retardation licensed in good standing by the department of inspections and appeals.

(9) Nursing facilities, intermediate care facilities for the mentally retarded, and hospitals enrolled as providers in the Iowa Medicaid program.

b. Staff training. The agency shall meet the following training requirements as a condition of providing respite care under the children's mental health waiver:

(1) Within one month of employment, staff members must receive the following training:

1. Orientation regarding the agency's mission, policies, and procedures; and

2. Orientation regarding HCBS philosophy and outcomes for rights and dignity for the children's mental health waiver in 77.46(1) "c."

(2) Within four months of employment, staff members must receive training regarding the following:

1. Serious emotional disturbance in children and provision of services to children with serious emotional disturbance;

2. Confidentiality;

3. Provision of medication according to agency policy and procedure;

4. Identification and reporting of child abuse;

5. Incident reporting;

6. Documentation of service provision;

7. Appropriate behavioral interventions; and

8. Professional ethics.

(3) Until a staff member receives the training identified in subparagraphs (1) and (2), the staff member shall not provide any direct service without the oversight of supervisory staff and shall obtain feedback from the family within 24 hours of service provision.

(4) Within the first year of employment, staff members must complete 24 hours of training in children's mental health issues.

(5) During each consecutive year of employment, staff members must complete 12 hours of training in children's mental health issues.

c. Consumer-specific information. The following information must be written, current, and accessible to the respite provider during service provision:

(1) The consumer's legal and preferred name, birth date, and age, and the address and telephone number of the consumer's usual residence.

(2) The consumer's typical schedule.

(3) The consumer's preferences in activities and foods or any other special concerns.

(4) The consumer's crisis intervention plan.

d. Written notification of injury. The respite provider shall inform the parent, guardian or usual caregiver that written notification must be given to the respite provider of any recent injuries or illnesses that have occurred before respite provision.

e. Medication dispensing. Respite providers shall develop policies and procedures for the dispensing, storage, and recording of all prescription and nonprescription medications administered during respite provision. Home health agencies must follow Medicare regulations regarding medication dispensing.

f. Support of crisis intervention plan. As a condition of providing services under the children's mental health waiver, a respite provider shall develop and implement policies and procedures for maintaining the integrity of the individualized crisis intervention plan as defined in 441—24.1(225C) that is developed by each consumer's interdisciplinary team. The policies and procedures shall address:

(1) Sharing with the case manager and the interdisciplinary team information pertinent to the development of the consumer's crisis intervention plan.

(2) Training staff before service provision, in cooperation with the consumer's parents or legal guardian, regarding the consumer's individual mental health needs and individualized supports as identified in the crisis intervention plan.

(3) Ensuring that all staff have access to a written copy of the most current crisis intervention plan during service provision.

(4) Ensuring that the plan contains current and accurate information by updating the case manager within 24 hours regarding any circumstance or issue that would have an impact on the consumer's mental health or change the consumer's crisis intervention plan.

g. Service documentation. Documentation of respite care shall be made available to the consumer, parents, guardian, or usual caregiver upon request.

h. Capacity. A facility providing respite care under this subrule shall not exceed the facility's licensed capacity, and services shall be provided in a location and for a duration consistent with the facility's licensure.

i. Service provided outside home or facility. For respite care to be provided in a location other than the consumer's home or the provider's facility:

(1) The care must be approved by the parent, guardian or usual caregiver;

(2) The care must be approved by the interdisciplinary team in the consumer's service plan;

(3) The care must be consistent with the way the location is used by the general public; and

(4) Respite care in these locations shall not exceed 72 continuous hours.

This rule is intended to implement Iowa Code section 249A.4 and 2005 Iowa Acts, chapter 167, section 13, and chapter 117, section 3.

[ARC 7741B, IAB 5/6/09, effective 7/1/09; ARC 7936B, IAB 7/1/09, effective 9/1/09; ARC 9314B, IAB 12/29/10, effective 3/1/11; ARC 9487B, IAB 5/4/11, effective 7/1/11; ARC 1149C, IAB 10/30/13, effective 1/1/14]

441—77.47(249A) Health home services providers. Subject to the requirements of this rule, a designated provider may participate in the medical assistance program as a provider of health home services.

77.47(1) Qualifications. A designated provider of health home services must be a Medicaid-enrolled entity or provider that is determined through the provider enrollment process to have the systems and infrastructure in place to provide health home services.

a. Staffing. At a minimum, a qualifying provider must fill the following roles:

- (1) Designated practitioner.
- (2) Dedicated care coordinator.
- (3) Health coach.
- (4) Clinic support staff.

b. Data management. A qualifying provider shall ensure that all clinical data related to the member are maintained with the member's medical records through the use of health information technology.

c. Collaboration with case managers. Health homes providing services to members eligible pursuant to 441—subparagraph 78.53(2)“a”(1) or (2) must collaborate, at least quarterly, with targeted case managers, other case managers, or DHS service workers for each member receiving case management services. Strategies to prevent duplication of coordination efforts by the health home and case managers or service workers must be developed by the health home and documented upon request. Documentation may include but is not limited to records of joint staffing meetings where a member's medical needs, current activities, and waiver services needs are reviewed and appropriately updated.

d. Provision of integrated health home services. Health homes providing services to members eligible pursuant to 441—subparagraph 78.53(2)“a”(3) or (4) must be integrated health homes that:

- (1) Consist of a team of health care professionals trained in providing health home services to members with a serious mental illness (SMI) and to members with a serious emotional disturbance (SED);
- (2) Have a direct agreement with the Iowa Medicaid managed behavioral health organization to provide health home services for members with SMI or SED;
- (3) Coordinate all community and social support services needs for members enrolled in the health home; and
- (4) Follow a system of care model in providing health home services to members with SED, including collaboration with the child welfare, public health, juvenile justice, and education systems.

77.47(2) Report on quality measures. As a condition of participation in the medical assistance program as a provider of health home services and of receiving payment for health home services provided, a designated provider must report to the Iowa Medicaid enterprise on measures for determining the quality of such services. When appropriate and feasible, a designated provider shall use health information technology in providing the Iowa Medicaid enterprise with such information.

77.47(3) Selection. As a condition of payment for health home services provided to a Medicaid member eligible to receive such services pursuant to 441—subrule 78.53(2), a designated provider must be selected by the member as the member's health home, as reported by provider attestation.

This rule is intended to implement Iowa Code section 249A.4 and 2011 Iowa Acts, chapter 129, section 10.

[ARC 0198C, IAB 7/11/12, effective 7/1/12; ARC 0838C, IAB 7/24/13, effective 7/1/13]

441—77.48(249A) Speech-language pathologists. Speech-language pathologists who are enrolled in the Medicare program are eligible to participate in Medicaid. Speech-language pathologists who are not enrolled in the Medicare program are eligible to participate in Medicaid if they are licensed and in independent practice, as an individual or as a group.

77.48(1) Speech-language pathologists in another state are eligible to participate if they are licensed in that state and meet the Medicare criteria for enrollment.

77.48(2) Speech-language pathologists who provide services to Medicaid members who are also Medicare beneficiaries must be enrolled in the Medicare program.

This rule is intended to implement Iowa Code section 249A.4 and 2012 Iowa Acts, Senate File 2158. [ARC 0360C, IAB 10/3/12, effective 12/1/12]

441—77.49(249A) Physician assistants. All physician assistants licensed to practice in the state of Iowa are eligible for participation in the program. Physician assistants duly licensed to practice in other states are also eligible for participation. Enrollment is for the purpose of providing professional services for Medicaid members including orders and referrals, as required under Public Law 111-148, Section 6401, otherwise known as the Patient Protection and Affordable Care Act (PPACA). Enrollment will not affect the provider's payment arrangements with facilities or supervising providers.

This rule is intended to implement Iowa Code section 249A.4. [ARC 0580C, IAB 2/6/13, effective 4/1/13]

441—77.50(249A) Ordering and referring providers. A provider who provides services, including orders and referrals, to a Medicaid member shall be enrolled as a Medicaid provider as a condition of payment eligibility for services rendered to that Medicaid member. A provider who does not individually bill for services rendered due to, for example, payment arrangements with a facility or supervising provider, shall also be required to enroll. Enrollment will be for the purpose of ordering or referring items and providing professional services to Medicaid members and will not affect the provider's payment arrangements with such facilities or supervising providers.

This rule is intended to implement Iowa Code section 249A.4. [ARC 0580C, IAB 2/6/13, effective 4/1/13]

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CHAPTER 110
CHILD DEVELOPMENT HOMES

[Prior to 7/1/83, Social Services[770] Ch 110]

[Prior to 2/11/87, Human Services[498]]

PREAMBLE

This chapter establishes registration procedures for child development homes. Included are application and renewal procedures, standards for providers, and procedures for compliance checks and complaint investigation.

441—110.1(237A) Definitions.

“Adult” means a person aged 18 or older.

“Assistant” means a responsible person aged 14 or older. The assistant may never be left alone with children. Ultimate responsibility for supervision is with the child care provider.

“Child” means either of the following:

1. A person 12 years of age or younger.
2. A person 13 years of age or older but younger than 19 years of age who has a developmental disability, as defined under the federal Developmental Disabilities Assistance and Bill of Rights Act of 2000, Public Law No. 106-402, codified in 42 U.S.C. 15002(8).

“Child care” means the care, supervision, or guidance of a child by a person other than the child’s parent, guardian, or custodian for periods of less than 24 hours per day per child on a regular basis. Child care shall not mean special activity programs that meet on a regular basis such as music or dance classes, organized athletics or sports programs, scouting programs, or hobby or craft classes or clubs.

“Child care facility” or *“facility”* means a child care center, a preschool, or a registered child development home.

“Child care home” means a person or program providing child care to five or fewer children at any one time that is not registered to provide child care under this chapter, as authorized under Iowa Code section 237A.3.

“Child development home” means a person or program registered under this chapter that may provide child care to six or more children at any one time.

“Department” means the department of human services.

“Involvement with child care” means licensed or registered as a child care facility, employed in a child care facility, residing in a child care facility, receiving public funding for providing child care, providing child care as a child care home provider, or residing in a child care home.

“Parent” means parent or legal guardian.

“Part-time hours” means the hours that child development homes in categories B and C are allowed to exceed their maximum preschool or school-age capacity. A provider may use a total of up to 180 hours per month as part-time hours. No more than two children using part-time hours may be in the child development home at any one time.

“Person subject to an evaluation” means a person who has committed a transgression and who is described by any of the following:

1. The person is being considered for registration or is registered.
2. The person is being considered by a child care facility for employment involving direct responsibility for a child or with access to a child when the child is alone, or the person is employed with such responsibilities.
3. The person will reside or resides in a child care facility.
4. The person has applied for or receives public funding for providing child care.
5. The person will reside or resides in a child care home that is not registered but that receives public funding for providing child care.

“Provider” means the person or program that applies for registration to provide child care and is approved as a child development home.

“Registration” means the process by which child care providers certify that they comply with rules adopted by the department.

“Registration certificate” means the written document issued by the department to publicly state that the provider has certified in writing compliance with the minimum requirements for registration of a child development home.

“School” means kindergarten or a higher grade level.

“Transgression” means the existence of any of the following in a person’s record:

1. Conviction of a crime.
2. A record of having committed founded child or dependent adult abuse.
3. Listing in the sex offender registry established under Iowa Code chapter 692A.
4. A record of having committed a public or civil offense.
5. Department revocation or denial of a child care facility registration or license due to the person’s continued or repeated failure to operate the child care facility in compliance with licensing and registration laws and rules.

441—110.2(237A) Application for registration. A provider shall apply for registration on Form 470-3384, Application for Child Development Home Registration, provided by the department’s local office or, if available, on the department’s Web site. The provider shall also use Form 470-3384 to inform the department of any changes in circumstances that would affect the registration.

441—110.3(237A) Renewal. Renewal of registration shall be completed every 24 months. To request renewal, a provider shall submit Form 470-3384, Application for Child Development Home Registration, and copies of certificates of training, to be retained in the registration file. The renewal process shall include completion of child abuse, sex offender, and criminal record checks.

441—110.4(237A) Number of children. The number of children shall conform to the following standards:

110.4(1) Limit. Except as provided in subrule 110.4(3), no greater number of children shall be received for care at any one time than the number authorized on the registration certificate.

110.4(2) Children counted. In determining the number of children cared for at any one time in a child development home, each child present in the child development home shall be considered to be receiving care unless the child is described by one of the following exceptions:

a. The child’s parent, guardian, or custodian established or operates the child development home and either the child is attending school or the child receives child care full-time on a regular basis from another person.

b. The child has been present in the child development home for more than 72 consecutive hours and meets the requirements of the exception in paragraph “a” as though the person who established or operates the child development home is the child’s parent, guardian, or custodian.

110.4(3) Exception for emergency school closing. On days when schools are closed due to emergencies such as inclement weather or physical plant failure, a child development home may have additional children present in accordance with the authorization for the registration category of the home and subject to all of the following conditions:

a. The child development home has prior written approval from the parent or guardian of each child present in the home concerning the presence of additional children in the home.

b. The child development home has a department-approved assistant, aged 14 or older, on duty to assist the care provider, as required for the registration category of the home.

c. One or more of the following conditions are applicable to each of the additional children present in the child development home:

- (1) The home provides care to the child on a regular basis for periods of less than two hours.
- (2) If the child were not present in the child development home, the child would be unattended.
- (3) The home regularly provides care to a sibling of the child.

d. The provider shall maintain a written record including the date of the emergency school closing, the reason for the closing, and the number of children in care on that date.

441—110.5(237A) Standards. The provider shall certify that the child development home meets the following standards and also the standards in either rule 441—110.8(237A), 441—110.9(237A), or 441—110.10(237A), specific to the category of home for which the provider requests registration.

110.5(1) Health and safety. Conditions in the home shall be safe, sanitary, and free of hazards.

a. The home shall have a non-pay, working telephone with emergency numbers posted for police, fire, ambulance, and the poison information center. The number for each child's parent, for a responsible person who can be reached when the parent cannot, and for the child's physician shall be written on paper and readily accessible by the telephone. The home must prominently display all emergency information, and a paper copy of emergency parent contact information must be kept in all travel vehicles. If the working telephone is a mobile telephone, all emergency numbers must also be programmed and saved into the telephone.

b. All medicines and poisonous, toxic, or otherwise unsafe materials shall be secured from access by a child.

c. A first-aid kit shall be available and easily accessible whenever children are in the child development home, in the outdoor play area, in vehicles used to transport children, and on field trips. The kit shall be sufficient to address first aid related to minor injury or trauma and shall be stored in an area inaccessible to children.

d. Medications shall be given only with the parent's or doctor's written authorization. Each prescribed medication shall be accompanied by a physician's or pharmacist's direction. Both nonprescription and prescription medications shall be in the original container with directions intact and labeled with the child's name. All medications shall be stored properly and, when refrigeration is required, shall be stored in a separate, covered container so as to prevent contamination of food or other medications. All medications shall be stored so they are inaccessible to children.

e. Electrical wiring shall be maintained with all accessible electrical outlets safely capped and electrical cords properly used. Improper use includes running cords under rugs, over hooks, through door openings, or other use that has been known to be hazardous.

f. Combustible materials shall be kept away from furnaces, stoves, water heaters, and gas dryers.

g. Approved safety gates at stairways and doors shall be provided and used as needed.

h. A safe outdoor play area shall be maintained in good condition throughout the year. The play area shall be fenced off when located on a busy thoroughfare or near a hazard which may be injurious to a child, and shall have both sunshine and shade areas. The play area shall be kept free from litter, rubbish, and flammable materials and shall be free from contamination by drainage or ponding of sewage, household waste, or storm water.

i. Annual laboratory analysis of a private water supply shall be conducted to show satisfactory bacteriological quality. When children under the age of two are to be cared for, the analysis shall include a nitrate analysis. When private water supplies are determined unsuitable for drinking, commercially bottled water or water treated through a process approved by the health department or designee shall be provided.

j. Emergency plans in case of man-made or natural disaster shall be written and posted by the primary and secondary exits. The plans shall clearly map building evacuation routes and tornado and flood shelter areas.

k. Fire and tornado drills shall be practiced monthly and the provider shall keep documentation evidencing compliance with monthly practice on file.

l. A safety barrier shall surround any heating stove or heating element, in order to prevent burns.

m. The home shall have at least one 2A 10BC rated fire extinguisher located in a visible and readily accessible place on each child-occupied floor.

n. The home shall have at least one single-station, battery-operated, UL-approved smoke detector in each child-occupied room and at the top of every stairway. Each smoke detector shall be installed

according to manufacturer's recommendations. The provider shall test each smoke detector monthly and keep a record of testing for inspection purposes.

o. Smoking and the use of tobacco products shall be prohibited at all times in the home and in every vehicle in which children receiving care in the home are transported. Smoking and the use of tobacco products shall be prohibited in the outdoor play area during the home's hours of operation. Nonsmoking signs shall be posted at every entrance of the child care home and in every vehicle used to transport children. All signs shall include:

- (1) The telephone number for reporting complaints, and
- (2) The Internet address of the department of public health (www.iowasmokefreeair.gov).

p. Children under the age of one year shall be placed on their backs when sleeping unless otherwise authorized in writing by a physician.

q. Providers shall inform parents of the presence of any pet in the home.

(1) Each dog or cat in the household shall undergo an annual health examination by a licensed veterinarian. Acceptable veterinary examinations shall be documented on Form 470-5153, Veterinary Health Certificate. This examination shall verify that the animal's routine immunizations, particularly rabies, are current and that the animal shows no evidence of endoparasites (roundworms, hookworms, whipworms) and ectoparasites (fleas, mites, ticks, lice).

(2) Each pet bird in the household shall be purchased from a dealer licensed by the Iowa department of agriculture and land stewardship and shall be examined by a veterinarian to verify that it is free of infectious diseases. Acceptable veterinary examinations shall be documented on Form 470-5153, Veterinary Health Certificate. Children shall not handle pet birds.

(3) Aquariums shall be well maintained and installed in a manner that prevents children from accessing the water or pulling over a tank.

(4) All animal waste shall be immediately removed from the children's areas and properly disposed of. Children shall not perform any feeding or care of pets or cleanup of pet waste.

(5) No animals shall be allowed in the food preparation, food storage, or serving areas during food preparation and serving times.

r. When there is a swimming or wading pool on the premises:

(1) A wading pool shall be drained daily and shall be inaccessible to children when it is not in use.

(2) An aboveground or in-ground swimming pool that is not fenced shall be covered whenever the pool is not in use. The cover shall meet or exceed the standards of the American Society for Testing and Materials.

(3) An uncovered aboveground swimming pool shall be enclosed with an approved fence that is four feet above the side walls.

(4) An uncovered in-ground swimming pool shall be enclosed with a fence that is at least four feet high and flush with the ground.

s. If children are allowed to use an aboveground or in-ground swimming pool:

(1) Written permission from parents shall be available for review.

(2) Equipment needed to rescue a child or adult shall be readily accessible.

(3) The child care provider shall accompany the children and provide constant supervision while the children use the pool.

(4) The child care provider shall complete training in cardiopulmonary resuscitation for infants, toddlers, and children, according to the criteria of the American Red Cross or the American Heart Association.

t. Homes served by private sewer systems shall be compliant with environmental protection commission rules on wastewater treatment and disposal systems at 567—Chapter 69. Compliance shall be verified by the local board of health within 12 months of renewal or new registration.

u. The provider shall have written policies regarding the care of mildly ill children and exclusion of children due to illness and shall inform parents of these policies.

v. The provider shall have written policy and procedures for responding to health-related emergencies.

w. The provider shall document all injuries that require first aid or medical care using an injury report form. The form shall be completed on the date of occurrence, shared with the parent, and maintained in the child's file.

x. A provider operating in a facility built before 1960 shall assess and control lead hazards before being issued an initial child development home registration or a renewal of the registration. To comply with this requirement, the provider shall:

(1) Conduct a visual assessment of the facility for lead hazards that exist in the form of peeling or chipping paint;

(2) Apply interim controls on any chipping or peeling paint found, using lead-safe work methods in accordance with and as defined by department of public health rules at 641—Chapters 69 and 70, unless a certified inspector as defined in 641—Chapter 70 determines that the paint is not lead-based paint; and

(3) Submit Form 470-4755, Lead Assessment and Control, as verification of the visual assessment and completion of interim controls, if necessary.

EXCEPTION: Providers that have a valid registration on November 1, 2009, shall assess and control lead hazards by June 30, 2010.

110.5(2) Provider files. A provider file shall be maintained and shall contain the following:

a. A physical examination report. Providers and all members of a provider's household shall have good health as evidenced by a preregistration physical examination. Acceptable physical examinations shall be documented on Form 470-5152, Child Care Provider Physical Examination Report. The examination shall include any necessary testing for communicable diseases; shall include a discussion regarding current Advisory Committee on Immunization Practices (ACIP)-recommended vaccinations; shall be performed within six months prior to registration by a licensed medical doctor, doctor of osteopathy, physician assistant or advanced registered nurse practitioner; and shall be repeated at least every three years.

b. Certificates or other documentation from the department verifying the following:

(1) Required training as set forth in subrule 110.5(11).

(2) Completion of all record checks as required in subrule 110.7(3), at initial application, at each application for change and at each application for renewal.

c. An individual file for each staff assistant that contains:

(1) Documentation from the department confirming the record checks required under subrule 110.7(3) have been completed and authorizing or conditionally limiting the person's involvement with child care.

(2) A completed Form 470-5152, Child Care Provider Physical Examination Report, that meets the requirements of paragraph 110.5(2) "a."

(3) Certification of a minimum of two hours of approved training relating to the identification and reporting of child abuse, completed within six months of employment and every five years thereafter, as required by Iowa Code section 232.69.

d. An individual file for each substitute that contains:

(1) Documentation from the department confirming the record checks required under subrule 110.7(3) have been completed and authorizing or conditionally limiting the person's involvement with child care.

(2) A completed Form 470-5152, Child Care Provider Physical Examination Report, that meets the requirements of paragraph 110.5(2) "a."

(3) Certification of a minimum of two hours of approved training relating to the identification and reporting of child abuse, completed within six months of employment and every five years thereafter, as required by Iowa Code section 232.69.

(4) Certification in first aid that meets the requirements of paragraph 110.5(11) "b."

110.5(3) Activity program. There shall be an activity program which promotes self-esteem and exploration and includes:

a. Active play.

b. Quiet play.

c. Activities for large muscle development.

- d.* Activities for small muscle development.
- e.* Play equipment and materials in a safe condition, for both indoor and outdoor activities which are developmentally appropriate for the ages and number of children present.

110.5(4) The certificate of registration shall be displayed in a conspicuous place.

110.5(5) Parental access. Parents shall be afforded unlimited access to their children and to the people caring for their children during the normal hours of operation or whenever their children are in the care of the child development home, unless parental contact is prohibited by court order.

110.5(6) Discipline. Discipline shall conform to the following standards:

- a.* Corporal punishment including spanking, shaking and slapping shall not be used.
- b.* Punishment which is humiliating or frightening or which causes pain or discomfort to the child shall not be used.
- c.* Punishment shall not be administered because of a child's illness, or progress or lack of progress in toilet training, nor shall punishment or threat of punishment be associated with food or rest.
- d.* No child shall be subjected to verbal abuse, threats, or derogatory remarks about the child or the child's family.
- e.* Discipline shall be designed to help the child develop self-control, self-esteem, and respect for the rights of others.

110.5(7) Meals. Regular meals and midmorning and midafternoon snacks shall be provided which are well-balanced, nourishing, and in appropriate amounts as defined by the USDA Child and Adult Care Food Program. Children may bring food to the child development home for their own consumption, but shall not be required to provide their own food.

110.5(8) Children's files. An individual file shall be maintained for each child and updated annually or when the provider becomes aware of changes. The file shall contain:

- a.* Identifying information including, at a minimum, the child's name, birth date, parent's name, address, telephone number, special needs of the child, and the parent's work address and telephone number.
- b.* Emergency information including, at a minimum, where the parent can be reached, the name, street address, city and telephone number of the child's regular source of health care, and the name, telephone number, and relationship to the child of another adult available in case of emergency.
- c.* A signed medical consent from the parent authorizing emergency treatment.
- d.* An admission physical examination report signed by a licensed physician or designee in a clinic supervised by a licensed physician.
 - (1) The date of the physical examination shall not be more than 12 months before the child's first day of attendance at the child development home.
 - (2) The written report shall include past health history, status of present health, allergies and restrictive conditions, and recommendations for continued care when necessary.
 - (3) For a child who is five years of age or older and enrolled in school, a statement of health status signed by the parent or legal guardian may be substituted for the physical examination report.
 - (4) The examination report or statement of health status shall be on file before the child's first day of care.
- e.* A statement of health condition signed by a physician or designee submitted annually from the date of the admission physical. For a child who is five years of age or older and enrolled in school, a statement of health status signed by the parent or legal guardian may be substituted for the physician statement.
- f.* A list signed by the parent which names persons authorized to pick up the child. The authorization shall include the name, telephone number, and relationship of the authorized person to the child.
- g.* A signed and dated immunization certificate provided by the state department of public health. For the school-age child, a copy of the most recent immunization record shall be acceptable.
- h.* For each school-age child, on the first day of attendance, documentation of a physical examination that was completed at the time of school enrollment or since.

i. Written permission from the parent for the child to attend activities away from the child development home. The permission shall include:

- (1) Times of departure and arrival.
- (2) Destination.
- (3) Persons who will be responsible for the child.

j. Injury report forms documenting injuries requiring first aid or medical care.

110.5(9) Provider. The provider shall meet the following requirements:

- a.* Give careful supervision at all times.
- b.* Exchange information with the parent of each child frequently to enhance the quality of care.
- c.* Give consistent, dependable care and be capable of handling emergencies.
- d.* Be present at all times except when emergencies occur or an absence is planned, at which time care shall be provided by a department-approved substitute. When an absence is planned, the provider shall give parents at least 24 hours' prior notice.

110.5(10) Substitutes. The provider shall assume responsibility for providing adequate and appropriate supervision at all times when children are in attendance. Any designated substitute shall have the same responsibility for providing adequate and appropriate supervision. Ultimate responsibility for supervision shall be with the provider.

- a.* All standards in this chapter regarding supervision and care of children shall apply to substitutes.
- b.* Except in emergency situations, the provider shall inform parents in advance of the planned use of a substitute.

c. The substitute must be 18 years of age or older.

d. Use of a substitute shall be limited to:

- (1) No more than 25 hours per month.
- (2) An additional period of up to two weeks in a 12-month period.

e. The provider shall maintain a written record of the number of hours substitute care is provided, including the date and the name of the substitute.

110.5(11) Professional development.

a. The provider shall receive two hours of Iowa's training for mandatory reporting of child abuse:

- (1) During the first three months of registration as a child development home; and
- (2) Every five years thereafter.

b. The provider shall obtain first-aid training within the first three months of registration as a child development home.

(1) First-aid training shall be provided by a nationally recognized training organization, such as the American Red Cross, the American Heart Association, the National Safety Council, or Emergency Medical Planning (Medic First Aid) or by an equivalent trainer using curriculum approved by the department.

(2) First-aid training shall include certification in infant and child first aid that includes management of a blocked airway and mouth-to-mouth resuscitation.

(3) The provider shall maintain a valid certificate indicating the date of first-aid training and the expiration date.

c. During the first year of registration, the provider shall receive a minimum of 12 hours of training from one or more of the following content areas. The provider shall receive at least 6 of these hours in a group setting as defined in subrule 110.5(12), and 2 of the hours must be from the content area in subparagraph 110.5(11)"c"(1). A provider shall not use a specific training or class to meet minimum continuing education requirements more than one time every five years.

(1) Planning a safe, healthy learning environment (includes nutrition).

(2) Steps to advance children's physical and intellectual development.

(3) Positive ways to support children's social and emotional development (includes guidance and discipline).

(4) Strategies to establish productive relationships with families (includes communication skills and cross-cultural competence).

(5) Strategies to manage an effective program operation (includes business practices).

- (6) Maintaining a commitment to professionalism.
- (7) Observing and recording children's behavior.
- (8) Principles of child growth and development.

d. During the second year of registration and each succeeding year, the provider shall receive a minimum of 12 hours of training from one or more of the content areas as defined in paragraph "c." The provider shall receive at least 6 of these hours in a group setting as defined in subrule 110.5(12). The provider may receive the remaining hours in self-study as defined in subrule 110.5(13). A provider shall not use a specific training or class to meet minimum continuing education requirements more than one time every five years.

e. A provider who submits documentation from a child care resource and referral agency that the provider has completed the Iowa Program for Infant/Toddler Care (IA PITC), ChildNet, or Beyond Business Basics training series may use those hours to fulfill a maximum of two years' training requirements, not including first-aid and mandatory reporter training.

110.5(12) Group training. Training received in a group setting is not self-study, but is training received with other adults.

a. The training must be conducted by a trainer who is employed by or under contract with one of the following entities or who uses curriculum or training materials developed by or obtained with the written permission of one of the following entities:

- (1) An accredited university or college.
- (2) A community college.
- (3) Iowa State University Extension.
- (4) A child care resource and referral agency.
- (5) An area education agency.
- (6) The regents' center for early developmental education at the University of Northern Iowa.
- (7) A hospital (for health and safety, first-aid, and CPR training).
- (8) The American Red Cross, the American Heart Association, the National Safety Council, or Medic First Aid (for first-aid and CPR training).
- (9) An Iowa professional association, including the Iowa Association for the Education of Young Children (Iowa AEYC), the Iowa Family Child Care Association (IFCCA), the Iowa After School Alliance, and the Iowa Head Start Association.
- (10) A national professional association, including the National Association for the Education of Young Children (NAEYC), the National Child Care Association (NCCA), the National Association for Family Child Care (NAFCC), the National After School Association, and the American Academy of Pediatrics.
- (11) The Child and Adult Care Food Program and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).
- (12) The Iowa department of public health, department of education, or department of human services.
- (13) Head Start agencies or the Head Start technical assistance system.

b. Training received in a group setting must follow a presentation format that incorporates a variety of adult learning methods. The material or content of the training must be obtained from one of the entities listed in paragraph "a" or an entity approved under paragraph "g." Approved training shall be made available to Iowa child care providers through the child care provider training registry beginning July 1, 2009.

c. Training received in a group setting may include distance learning opportunities such as training conducted over the Iowa communications network, on-line courses, or Web conferencing (webinars) if:

- (1) The training meets the requirements in subrule 110.5(14);
- (2) The training is taught by an instructor and requires interaction between the instructor and the participants, such as required chats or message boards; and
- (3) The training organization meets the requirements listed in this subrule or is approved by the department.

d. The department will not approve more than eight hours of training delivered in a single day.

e. The department may randomly monitor any state-approved training for quality control purposes.

f. Training conducted with staff either during the hours of operation of the facility, staff lunch hours, or while children are resting must not diminish the required staff ratio coverage. Staff shall not be actively engaged in care and supervision and simultaneously participate in training.

g. A training organization not approved by the department may submit training for approval to the department on Form 470-4528, Request for Child Care Training Approval. All approvals, unless otherwise specified, shall be valid for five years. The department shall issue its decision within 30 business days of receipt of a complete request.

110.5(13) Self-study training. Up to six hours of training may be received in self-study using a training package approved by the department.

a. Self-study training packages approved by the department include curriculum developed and materials distributed by:

- (1) Department child care licensing consultants,
- (2) Iowa State University Extension, or
- (3) A child care resource and referral agency.

b. Self-study training materials not distributed by these entities may be submitted by the training organization to the department for approval on Form 470-4528, Request for Child Care Training Approval. All approvals, unless otherwise specified, shall be valid for five years. The department shall issue its decision within 30 business days of receipt of a complete request.

110.5(14) Approved training. Training provided to Iowa child care providers shall offer:

a. Instruction that is consistent with:

- (1) Iowa child care regulatory standards;
- (2) The Iowa early learning standards; and
- (3) The philosophy of developmentally appropriate practice as defined by the National Association for the Education of Young Children, the Program for Infant/Toddler Care, and the National Health and Safety Performance Standards.

b. Content equal to at least one contact hour of training.

c. An opportunity for ongoing interaction and timely feedback, including questions and answers within the contact hours if training is delivered in a group setting.

d. A certificate of training for each participant that includes:

- (1) The name of the participant.
- (2) The title of the training.
- (3) The dates of training.
- (4) The content area addressed.
- (5) The name of the training organization.
- (6) The name of the instructor.
- (7) The number of contact hours.
- (8) An indication of whether the training was delivered through self-study or in a group setting.

[ARC 8098B, IAB 9/9/09, effective 11/1/09; ARC 0666C, IAB 4/3/13, effective 6/1/13; ARC 0996C, IAB 9/4/13, effective 11/1/13; ARC 1636C, IAB 10/1/14, effective 1/1/15]

441—110.6(237A) Compliance checks. During a calendar year, the department shall seek to check 100 percent of all child development homes in each county for compliance with registration requirements. Completed evaluation checklists shall be placed in the registration files.

[ARC 1637C, IAB 10/1/14, effective 1/1/15]

441—110.7(234) Registration decision. The department shall issue Form 470-3498, Certificate of Registration, when an applicant meets all requirements for registration. Each local office of the department shall maintain a current list of registered child development homes as a referral service to the community.

110.7(1) Registration shall be denied or revoked if the department finds a hazard to the safety and well-being of a child and the provider cannot correct or refuses to correct the hazard, even though the hazard may not have been specifically listed under the health and safety rules. Registration may also

be denied or revoked if the department determines that the provider has failed to comply with standards imposed by law and these rules.

110.7(2) Record shall be kept in an open file of all denials or revocations of registration and the documentation of reasons for denying or revoking the registration.

110.7(3) Record checks.

a. Applicability. The department shall conduct Iowa criminal history record and child abuse record checks for each registrant, substitute or staff member, anyone living in the home who is 14 years of age or older, and anyone having access to a child when the child is alone. The department shall conduct national criminal history record checks, based on fingerprints, for each registrant, substitute or staff member, anyone living in the home who is 18 years of age or older, and anyone 18 years of age or older having access to a child when the child is alone. In accordance with Iowa Code section 726.23, minors under the age of 18 will not be subject to the fingerprint requirement.

(1) The purpose of these record checks is to determine whether the person has committed a transgression that prohibits or limits the person's involvement with child care.

(2) The department may also conduct criminal history record and child abuse record checks in other states and may conduct dependent adult abuse, sex offender registry, and other public or civil offense record checks in Iowa or other states.

(3) Effective July 1, 2013, registration or renewal certificates shall not be issued until the results of all state and national record checks have been received and, when necessary, evaluated.

b. Authorization. The person subject to record checks shall complete Form 470-5143, Iowa Department of Human Services Record Check Authorization Form; Form DCI-45, Waiver Agreement; Form FD-258, Federal Fingerprint Card; and any other forms required by the department of public safety to authorize the release of records.

c. Iowa records checks. Checks and evaluations of Iowa child abuse and criminal history records shall be completed before the person's involvement with child care. Iowa records checks shall be repeated at a minimum of every two years and when the department or the registrant becomes aware of any possible transgressions. The department is responsible for the cost of conducting the Iowa records checks.

d. National criminal history record checks. Fingerprint-based checks of national criminal history records shall also be completed before a person's involvement with child care. This requirement shall be effective on or after July 1, 2013, for an initial application for registration or a renewal application for registration. The national criminal history record check shall be repeated for each person subject to the check every four years and when the department or registrant becomes aware of any new transgressions committed by that person in another state. The department is responsible for the cost of conducting the national criminal history record check.

(1) The registrant is responsible for any costs associated with the taking (rolling) of fingerprints of all persons subject to record checks and for submitting the prints to the department so the national criminal history record check can be completed. Fingerprints may be taken (rolled) by law enforcement agencies or by agencies or companies that specialize in taking (rolling) fingerprints.

(2) The department shall provide fingerprints to the department of public safety no later than ten business days after receipt of the fingerprint cards. The department shall submit the fingerprints on forms or in a manner allowed by the department of public safety.

(3) The department may rely on the results of previously conducted national criminal history record checks when a person subject to a record check in one child development home or child care home submits a request for involvement with child care in another child development home or child care home, so long as the person's national criminal history record check is within the allowable four-year time frame. All initial or new applications shall require a new national criminal history record check.

e. Mandatory prohibition. A person with any of the following convictions or founded abuse reports is prohibited from involvement with child care:

- (1) Founded child or dependent adult abuse that was determined to be sexual abuse.
- (2) Placement on the sex offender registry.
- (3) Felony child endangerment or neglect or abandonment of a dependent person.

- (4) Felony domestic abuse.
- (5) Felony crime against a child including, but not limited to, sexual exploitation of a minor.
- (6) Forcible felony.

f. Mandatory time-limited prohibition.

(1) A person with the following conviction or founded abuse report is prohibited from involvement with child care for five years from the date of the conviction or founded abuse report:

1. Conviction of a controlled substance offense under Iowa Code chapter 124.
2. Founded child abuse that was determined to be physical abuse.

(2) After the five-year prohibition period (from the date of the conviction or the founded abuse report) as defined in subparagraph 110.7(3) “f”(1), the person may request the department to perform an evaluation under paragraph 110.7(3) “g” to determine whether prohibition of the person’s involvement with child care continues to be warranted.

g. Evaluation required. For all other transgressions, and as requested under subparagraph 110.7(3) “f”(2), the department shall evaluate the transgression and make a decision about the person’s involvement with child care.

(1) The person with the transgression shall complete and return Form 470-2310, Record Check Evaluation, within ten calendar days of the date on the form. The department shall use the information the person with the transgression provides on this form to assist in the evaluation. Failure of the person with the transgression to complete and return this form within ten calendar days of the date on the form shall result in denial or revocation of the registration certificate.

(2) The department may use information from the department’s case records in performing the evaluation.

(3) In an evaluation, the department shall consider all of the following factors:

1. The nature and seriousness of the transgression in relation to the position sought or held.
2. The time elapsed since the commission of the transgression.
3. The circumstances under which the transgression was committed.
4. The degree of rehabilitation.
5. The likelihood that the person will commit the transgression again.
6. The number of transgressions committed by the person.

(4) When a person subject to a record check has a transgression that has been determined in a previous evaluation not to warrant prohibition of the person’s involvement with child care and the person has no subsequent transgressions, an exemption from reevaluation of the latest record check is authorized. The person may commence employment with another child care facility in accordance with the department’s previous evaluation. The exemption is subject to all of the following conditions:

1. The position with the subsequent employer is substantially the same or has the same job responsibilities as the position for which the previous evaluation was performed.

2. Any restrictions placed on the person’s employment by the department in the previous evaluation shall remain applicable in the person’s subsequent employment.

3. The person subject to the record check has maintained a copy of the previous evaluation and provides the evaluation to the subsequent employer or the previous employer provides to the subsequent employer the previous evaluation from the person’s personnel file pursuant to the person’s authorization. If a physical copy of the previous evaluation is not provided to the subsequent employer, the record check shall be reevaluated.

4. The subsequent employer may request a reevaluation of the record check and may employ the person while the reevaluation is being performed.

h. Evaluation decision. The department has final authority in determining whether prohibition of the person’s involvement with child care is warranted and in developing any conditional requirements or corrective action plan.

(1) Within 30 calendar days of receipt of a completed Form 470-2310, Record Check Evaluation, the department shall make a decision on the person’s involvement with child care.

(2) Within 30 calendar days of receipt of a completed Form 470-2310, Record Check Evaluation, the department shall mail to the person subject to an evaluation Form 470-2386, Record Check Decision,

that explains the decision reached regarding the evaluation of the transgression and Form 470-4558, Notice of Decision: Child Care.

(3) The department shall issue Form 470-4558, Notice of Decision: Child Care, prohibiting involvement with child care, when the person subject to an evaluation fails to complete the Record Check Evaluation, Form 470-2310, within the ten-calendar-day time frame.

(4) If the department determines, through the record check evaluation process, that the person's prohibition of involvement with child care is warranted, the person shall be prohibited from involvement with child care. The department may identify a period of time after which the person may request that another record check and evaluation be performed.

(5) The department may permit a person who is evaluated to maintain involvement with child care if the person complies with the department's conditions relating to the person's involvement with child care, which may include completion of additional training or an individually designed corrective action plan or both. For an employee of a registrant, these conditional requirements shall be developed with the registrant. All conditions placed on a person's involvement with child care shall be communicated, in writing, to both the person subject to the evaluation and the registrant.

i. Notice to parents of abuse in care. If there has been founded child abuse committed by an owner, director, or staff member of the child care facility or child care home, the department's administrator shall notify the parents, guardians, and legal custodians of each child for whom the facility or child care home provides care. The child care facility or child care home shall cooperate with the department in providing the names and addresses of the parents, guardians, and legal custodians of each child for whom the facility provides child care.

(1) The child care facility or child care home shall cooperate with the department in providing the names and addresses of the parent, guardian, or custodian of each child for whom the facility provides child care.

(2) This information shall be provided to the department within ten calendar days from the date of the initial request.

(3) Failure or refusal to provide the requested information may result in revocation of registration.

110.7(4) Letter of revocation. A letter received by an owner or operator of a child development home initiating action to deny or revoke the home's registration shall be conspicuously posted where it can be read by parents or any member of the public. The letter shall remain posted until resolution of the action to deny or revoke an owner's or operator's certificate of registration.

110.7(5) If the department has denied or revoked a registration because the provider has continually or repeatedly failed to operate in compliance with Iowa Code chapter 237A and 441—Chapter 110, the person shall not own or operate a registered facility for a period of 12 months from the date of denial or revocation. The department shall not act on an application for registration submitted by the applicant or provider during the 12-month period. The applicant shall be prohibited from involvement with child care unless the department specifically permits the involvement.

110.7(6) Required notifications. If a certificate of registration is revoked, the administrator of the department shall notify the parent, guardian, or legal custodian of each child for whom the facility provides care. The provider shall cooperate with the department in providing the names and address of the parent, guardian, or legal custodian of each child for whom the facility provides child care.

[ARC 0418C, IAB 10/31/12, effective 1/1/13; ARC 0715C, IAB 5/1/13, effective 7/1/13; ARC 1209C, IAB 12/11/13, effective 2/1/14]

441—110.8(237A) Additional requirements for child development home category A. In addition to the requirements in rule 441—110.5(237A), a provider requesting registration in child development home category A shall meet the following standards:

110.8(1) *Limits on number of children in care.*

a. No more than six children not attending kindergarten or a higher grade level shall be present at any one time.

b. Of these six children, not more than four children who are 24 months of age or younger shall be present at any one time. Of these four children, no more than three may be 18 months of age or younger.

c. In addition to the six children not in school, no more than two children who attend school may be present for a period of less than two hours at a time.

d. No more than eight children shall be present at any one time when an emergency school closing is in effect.

110.8(2) Provider qualifications.

a. The provider shall be at least 18 years old.

b. The provider shall have three written references which attest to character and ability to provide child care.

441—110.9(237A) Additional requirements for child development home category B. In addition to the requirements in rule 441—110.5(237A), a provider requesting registration in child development home category B shall meet the following standards:

110.9(1) Limits on number of children in care.

a. No more than six children not attending kindergarten or a higher grade level shall be present at any one time.

b. Of these six children, not more than four children who are 24 months of age or younger shall be present at any one time. Of these four children, no more than three may be 18 months of age or younger.

c. In addition to the six children not in school, no more than four children who attend school may be present.

d. In addition to these ten children, no more than two children who are receiving care on a part-time basis may be present.

e. No more than 12 children shall be present at any one time when an emergency school closing is in effect.

f. If more than eight children are present at any one time for a period of more than two hours, the provider shall be assisted by a department-approved assistant who is at least 14 years old.

110.9(2) Provider qualifications.

a. The provider shall be at least 20 years old.

b. The provider shall have a high school diploma or GED.

c. The provider shall either:

(1) Have two years of experience as a registered or nonregistered child care provider, or

(2) Have a child development associate credential or any two-year or four-year degree in a child-care-related field and one year of experience as a registered or nonregistered child care home provider.

110.9(3) Facility requirements.

a. The home shall have a minimum of 35 square feet of child-use floor space for each child in care indoors, and a minimum of 50 square feet per child in care outdoors.

b. The home shall have a separate quiet area for sick children.

c. The home shall have a minimum of two direct exits to the outside from the main floor.

(1) If the second level or the basement of the home is used for the provision of child care, other than the use of a restroom, each additional child-occupied floor shall have at least one direct exit to the outside in addition to one inside stairway.

(2) All exits shall terminate at grade level with permanent steps.

(3) A basement window may be used as an exit if the window can be opened from the inside without the use of tools and it provides a clear opening of not less than 20 inches in width, 24 inches in height, and 5.7 square feet in area. The bottom of the opening shall be not more than 44 inches above the floor, with permanent steps inside leading up to the window.

(4) Occupancy above the second floor shall not be permitted for child care.

441—110.10(237A) Additional requirements for child development home category C. In addition to the requirements in rule 441—110.5(237A), a provider requesting registration in child development home category C shall meet the following standards:

110.10(1) *Limits on number of children in care.*

- a. No more than 12 children not attending kindergarten or a higher grade level shall be present at any one time.
- b. Of these 12 children, not more than 4 children who are 24 months of age or younger shall be present at any one time. Whenever 4 children who are under the age of 18 months are in care, both providers shall be present.
- c. In addition to the 12 children not in school, no more than 2 children who attend school may be present for a period of less than two hours at any one time.
- d. In addition to these 14 children, no more than 2 children who are receiving care on a part-time basis may be present.
- e. No more than 16 children shall be present at any one time when an emergency school closing is in effect. If more than 8 children are present at any one time due to an emergency school closing exception, the provider shall be assisted by a department-approved assistant who is at least 18 years of age.
- f. If more than eight children are present, both providers shall be present. Each provider shall meet the provider qualifications for child development home category C.

110.10(2) *Provider qualifications.*

- a. One provider who meets the following qualifications must always be present:
 - (1) The provider shall be at least 21 years old.
 - (2) The provider shall have a high school diploma or GED.
 - (3) The provider shall either:
 1. Have five years of experience as a registered or nonregistered child care provider, or
 2. Have a child development associate credential or any two-year or four-year degree in a child care-related field and four years of experience as a registered or nonregistered child care home provider.
- b. The coprovider shall meet the requirements of subrule 110.9(2).

110.10(3) *Facility requirements.*

- a. The home shall have a minimum of 35 square feet of child-use floor space for each child in care indoors, and a minimum of 50 square feet per child in care outdoors.
- b. The home shall have a separate quiet area for sick children.
- c. The home shall have a minimum of two direct exits to the outside from the main floor.
 - (1) If the second level or the basement of the home is used for the provision of child care, other than the use of a restroom, each additional child-occupied floor shall have at least one direct exit to the outside in addition to one inside stairway.
 - (2) All exits shall terminate at grade level with permanent steps.
 - (3) A basement window may be used as an exit if the window can be opened from the inside without the use of tools and it provides a clear opening of not less than 20 inches in width, 24 inches in height, and 5.7 square feet in area. The bottom of the opening shall be not more than 44 inches above the floor, with permanent steps inside leading up to the window.
 - (4) Occupancy above the second floor shall not be permitted for child care.

441—110.11(237A) Complaints. The department shall conduct an on-site visit when a complaint is received.

110.11(1) After each complaint visit, the department shall document whether the child development home was in compliance with registration requirements.

110.11(2) The written documentation of the department's conclusion as to whether the child development home was in compliance with requirements shall be available to the public. However, the identity of all complainants shall be confidential, unless expressly waived by the complainant.

441—110.12(237A) Registration actions for nonpayment of child support. The department shall revoke or deny the issuance or renewal of a child development home registration upon the receipt of a certificate of noncompliance from the child support recovery unit of the department according to the

procedures in Iowa Code chapter 252J. In addition to the procedures set forth in Iowa Code chapter 252J, the rules in this chapter shall apply.

110.12(1) *Service of notice.* The notice required by Iowa Code section 252J.8 shall be served upon the applicant or registrant by restricted certified mail, return receipt requested, or personal service in accordance with Iowa Rules of Civil Procedure 56.1. Alternatively, the applicant or registrant may accept service personally or through authorized counsel.

110.12(2) *Effective date.* The effective date of the revocation or denial of the registration as specified in the notice required by Iowa Code section 252J.8 shall be 60 days following service of the notice upon the applicant or licensee.

110.12(3) *Preparation of notice.* The department director or designee of the director is authorized to prepare and serve the notice as required by Iowa Code section 252J.8 upon the applicant or registrant.

110.12(4) *Responsibilities of registrants and applicants.* Registrants and registrant applicants shall keep the department informed of all court actions, and all child support recovery unit actions taken under or in connection with Iowa Code chapter 252J, and shall provide the department copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 252J.9, all court orders entered in the actions, and withdrawals of certificates of noncompliance by the child support recovery unit.

110.12(5) *District court.* A registrant or applicant may file an application with the district court within 30 days of service of a department notice pursuant to Iowa Code sections 252J.8 and 252J.9.

a. The filing of the application shall stay the department action until the department receives a court order lifting the stay, dismissing the action, or otherwise directing the department to proceed.

b. For purposes of determining the effective date of the revocation, or denial of the issuance or renewal of a registration, the department shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

110.12(6) *Procedure for notification.* The department shall notify the applicant or registrant in writing through regular first-class mail, or such other means as the department deems appropriate in the circumstances, within ten days of the effective date of the revocation of a registration or the denial of the issuance or renewal of a registration, and shall similarly notify the applicant or registrant when the registration is issued, renewed, or reinstated following the department's receipt of a withdrawal of the certificate of noncompliance.

110.12(7) *Appeal rights.* Notwithstanding Iowa Code section 17A.18, the registrant does not have the right to a hearing regarding this issue, but may request a court hearing pursuant to Iowa Code section 252J.9.

441—110.13(237A) Transition exception. The following transition exceptions shall apply to providers renewing a valid previously issued child care home registration on or after December 1, 2002:

110.13(1) If the provider is providing child care to four infants at the time of renewal, the provider may continue to provide child care to those four infants. However, when the provider no longer provides child care to one or more of the four infants, or one or more of the four infants reaches the age of 24 months, this exception shall no longer apply. This exception does not affect the overall limit on the number of children in care under the child development home category within which the provider is registered.

110.13(2) If the provider is providing child care to school-age children in excess of the number allowable for the provider's registration category at the time of renewal, the provider may continue to provide care to those children and may exceed the total number of children authorized for that category by the excess number of school-age children. This exception is subject to the following conditions:

a. The maximum number of children attributable to this exception is five.

b. The provider must comply with the other requirements limiting the number of children under that registration category.

c. If more than eight children are present at any one time for more than two hours, the provider shall be assisted by a department-approved assistant who is at least 14 years of age.

d. When the provider no longer provides child care to one or more of the school-age children who was receiving child care at the time of registration, the excess number of children allowed under this exception shall be reduced accordingly.

441—110.14(237A) Prohibition from involvement with child care. If the department has prohibited a person or program from involvement with child care, that person or program shall not provide child care as a nonregistered child care home provider.

These rules are intended to implement Iowa Code section 234.6 and chapter 237A.

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NATURAL RESOURCE COMMISSION[571]

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[Prior to 12/31/86, Conservation Commission[290] Ch 30]

571—40.1(462A) Restricted areas. All vessels, except authorized emergency vessels, shall be operated in compliance with, and all persons engaged in water recreation activities, shall obey restrictions with posted areas marked with a uniform waterway buoy or official signs adopted by the natural resource commission.

571—40.2(462A) Uniform buoy system. All buoys placed shall be those of the uniform waterway marking system adopted by the natural resource commission and shall be constructed, placed, and maintained in accordance with Iowa Code chapter 462A and Iowa Administrative Code 571—Chapters 40 and 41.

571—40.3(462A) Commission approval. The placement of buoys or official signs that restrict speed and distance or involve special zoning restrictions shall be approved by the natural resource commission.

571—40.4(462A) Right for aggrieved party to appeal. Any finding or establishment of areas involving special speed and distance or zoning restrictions by the natural resource commission may be appealed by aggrieved party upon written notice. A hearing thereon shall be held by the natural resource commission within 30 days thereafter.

571—40.5(462A) Rathbun Lake, Appanoose County—zoned areas.

40.5(1) Areas may be specifically designated for swimming and wading.

40.5(2) Areas may be designated restricted speed areas.

571—40.6(462A) Red Rock Lake, Marion County—zoned areas.

40.6(1) Areas may be specifically designated for swimming and wading.

40.6(2) Areas may be designated restricted speed areas.

40.6(3) Areas may be designated as “no anchoring” areas.

571—40.7(462A) Coralville Lake, Johnson County—zoned areas.

40.7(1) Areas may be specifically designated for swimming and wading.

40.7(2) Areas may be designated restricted speed areas.

571—40.8(462A) Saylorville Lake, Polk County—zoned areas.

40.8(1) Areas may be specifically designated for swimming and wading.

40.8(2) Areas may be designated restricted speed areas.

571—40.9(462A) Lake Odessa in Louisa County.

40.9(1) Areas may be designated restricted speed areas.

40.9(2) All motorboats, except authorized emergency vessels, shall be operated at a speed not greater than 5 miles per hour year around, on that portion of Lake Odessa known as the Sand Run Chute, lying south of the main lake to a point 100 yards south of the Sand Run Chute boat ramp.

40.9(3) All motorboats, except authorized emergency vessels, shall be operated at a speed not greater than 5 miles per hour year around, on those portions of Lake Odessa known as the lateral ditch, between the main lake and Bebee Pond, and on the channel between Yankee Chute and Beaver Pond.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.10(462A) Mississippi River lock and dam safety zone. A safety zone is hereby established in Iowa waters above and below all navigation lock and dam structures on the Mississippi River between the Iowa-Minnesota border and the Iowa-Missouri border. The established zone shall be 600 feet upstream and 150 feet downstream from the roller gate or tainter gate section of the structure.

40.10(1) The safety zone does not include the area directly above and below the navigation lock structure.

40.10(2) The safety zone does not include the area directly above and below the solid fill portion of the dam and structure.

40.10(3) The safety zone shall be recognized by the state of Iowa only when plainly marked as follows:

- a. Upstream signs worded—Restricted area keep 600 feet from dam.
- b. Downstream signs worded—Restricted area keep 150 feet from dam.
- c. Flashing red lights will be used to make the outer limits of the restricted areas.

40.10(4) No boat or vessel of any type, except authorized vessels, shall enter the established safety zones recognized by the state of Iowa as described in this rule.

571—40.11(462A) Joyce Slough Area. The Joyce Slough Area, a portion of the Mississippi River within the city of Clinton, Iowa, is hereby zoned to be a harbor area and vessels traveling therein shall not travel at speeds in excess of five miles per hour.

571—40.12(462A) Swan Slough, Camanche, Iowa. A restricted speed zone of not greater than 5 miles per hour is hereby established in all or part of the main channel of Swan Slough (Mississippi River mile 510.2 to 511.3), Camanche, Iowa, as designated by buoys.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.13(462A) Massey Slough. The operation of vessels in Massey Slough of the Mississippi River at Massey Station, Dubuque County, Iowa, extending from a northerly to southerly direction from the upper end to the lower end of the slough, encompassing the water in Section 14, Township 88N, Range 3E of the 5th P.M., tract number NFIA-26M, is restricted as follows:

40.13(1) All boats underway must maintain a speed of less than five miles per hour in said waters.

40.13(2) Reserved.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.14(462A) Black Hawk County waters. Operation of vessels in Black Hawk County on the Cedar River and any connected backwaters shall be governed by this departmental rule as well as all applicable state laws and regulations.

40.14(1) No vessel, except authorized emergency vessels, shall be operated in marked areas at a speed greater than the limit designated by buoys, signs, or other approved uniform waterway marking devices marking the area.

40.14(2) All vessels, except authorized emergency vessels, shall be operated at a speed not greater than 5 miles per hour when within 600 feet of the Franklin Street bridge. This 600-foot zone shall be designated by buoys, signs, or other approved uniform waterway marking devices.

40.14(3) No vessel shall tow skiers, surfboard riders, or other towable devices within the zone established by 40.14(2).

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.15(462A) Mitchell County waters. Operation of vessels in Mitchell County is restricted to speeds not greater than 5 miles per hour where a speed zone is designated by buoys on the following impounded waters:

Cedar River from Mitchell Dam, thence upriver to the County “S” bridge.

Cedar River from the St. Ansgar Mill Dam, thence upriver to the Newberg Bridge crossing Highway 105.

Cedar River from the Otranto Dam upriver to the Great Western Railway Bridge crossing the Cedar River.

The Stacyville Pool, on the Little Cedar River at Stacyville, Iowa.

40.15(1) Water recreation activities as restricted within posted areas which are marked with approved buoys shall be obeyed.

40.15(2) Reserved.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.16(462A) Maquoketa River. Operation of vessels of the impoundment of the Maquoketa River in Delaware County, Iowa, extending westerly and northerly from the line between Sections 29 and 30 in Delhi Township in said county, to the line between Sections 10 and 15 in Milo Township in said county which impoundment is sometimes known and referred to as Hartwick Lake or Lake Delhi.

40.16(1) Water recreation activity restrictions shall be obeyed, including restrictions within posted areas which are marked with approved buoys.

40.16(2) No motorboat shall be operated at speeds greater than ten miles per hour at any time between the hours from one hour after sunset to one hour before sunrise.

571—40.17(462A) Zoning of off-channel waters of the Wapsipinicon River in Pinicon Ridge Park in Linn County. No motorboat shall be operated at a speed greater than 5 miles per hour within the zoned area designated by regulatory buoys or signs on the off-channel waters of the Wapsipinicon River above the dam at Central City, Linn County, Iowa.

The zoned area will be the off-channel waters created in and adjacent to the developed recreation areas of the Pinicon Ridge Park on the west and south bank of the Wapsipinicon River above the dam at Central City, Linn County.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.18(462A) Speed restrictions on Lake Manawa. No motorboat shall be operated at a speed greater than five miles per hour within the zoned areas 300 feet from shore around Lake Manawa in Pottawattamie County.

571—40.19(462A) Zoning of Little Wall Lake. No motorboat shall be operated at a speed greater than 5 miles per hour within the zoned area designated by regulatory buoys on Little Wall Lake in Hamilton County.

The zoned area will not exceed approximately 20 acres in the northeast portion of the lake identified by a line from a point on the high-water mark approximately 296.6 feet west of the southeast corner of the southwest quarter of Section 10, Township 86 North, Range 24 West; thence northwest to the high-water mark which is 775 feet south and 319 feet west of the northeast corner of the northwest quarter of the southwest quarter of Section 10, Township 86 North, Range 24 West.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.20(462A) Lake Icaria, Adams County—watercraft use. Motorboats of outboard or inboard-outdrive type shall be permitted on Lake Icaria. The following rules shall govern vessel operation on Lake Icaria in Adams County.

40.20(1) All vessels shall be operated at a speed not greater than 5 miles per hour when within 50 feet of another vessel which is not underway or is operating at a no-wake speed.

40.20(2) Zoned areas.

a. No vessel, except authorized emergency vessels, shall be permitted in areas specifically designated for swimming and wading which are plainly marked by the use of buoys or signs in accordance with 571—Chapter 41.

b. No motorboats, except authorized emergency vessels, shall be operated in marked bay areas at a speed greater than the limit designated by buoys or signs marking said bay. Said buoys or signs shall be in accordance with 571—Chapter 41.

c. No motorboats, except authorized emergency vessels, shall be operated in restricted speed areas between the nearest shore and a line designated by uniform marker buoys or signs at a speed greater than the limit designated on the buoys or signs marking the area. Such zoned areas shall be not less than 50 feet nor more than 400 feet from shore. Said buoys or signs shall be in accordance with 571—Chapter 41.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.21(462A) Zoning of the Des Moines River. Vessel operation on the Des Moines River from its confluence with the Mississippi River in Lee County to the northerly meander lines of both the East and West Branches, shall be governed by this departmental rule as well as all applicable state laws and regulations.

40.21(1) No vessel, except authorized emergency vessels, shall be operated in marked areas at a speed greater than the limit designated by buoys marking said areas.

40.21(2) No vessel, except authorized emergency vessels, shall be permitted in areas specifically designated for swimming and wading which are plainly marked by the use of buoys.

571—40.22(462A) Upper Gar Lake, Dickinson County. Operation of vessels on Upper Gar Lake is restricted to a speed not greater than 5 miles per hour between the Henshaw Bridge at the north end of Upper Gar and south end of East Lake and the Old Sawmill Bridge at the south end of Upper Gar and the north end of Minnewashta.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.23(462A) Zoning of the Mississippi River, Guttenberg river mile 616, Clayton County.

40.23(1) All vessels operated between the ice dike and Bussey Lake access shall be operated at a speed not greater than 5 miles per hour.

40.23(2) The city will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.24(462A) Mt. Ayr City Lake (Loch Ayr). A motorboat shall not be operated within 100 feet of shore at a speed greater than 5 miles per hour.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.25(462A) Iowa River in Iowa City, Johnson County. No person shall operate any vessel towing persons on water skis, surfboards, or similar devices on the Iowa River in the area bounded by the Coralville Mill Dam and the Burlington Street Dam, except during regattas, races, marine parades, tournaments, or exhibitions authorized by the natural resource commission to be held in such area.

571—40.26(462A) Zoning of the Mississippi River, Dubuque, Dubuque County.

40.26(1) All vessels shall be limited to no more than five miles per hour in Lake Peosta Cut south and east of the Hawthorn Street municipal boat launching ramp.

40.26(2) A restricted speed zone of no more than 5 miles per hour is established in the vicinity of Chaplain Schmitt Memorial Island in proximity to the Schmitt Island municipal launching ramp and in waters adjacent to the southerly shoreline in the area of the Dubuque Yacht Basin.

40.26(3) A restricted speed zone of five miles per hour for the northern portion of Shawondasse Slough. Marker buoys shall be placed at a point approximately 750 feet upstream from the existing speed zone.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.27(462A) Zoning Harpers Slough, Harpers Ferry, Allamakee County.

40.27(1) All vessels operated in Harpers Slough between a point 200 feet above the state ramp and 200 feet out from the west shore and extending 550 feet downstream from a point known as Sandy Point Road Dead-End shall operate at a speed not greater than 5 miles per hour.

40.27(2) The city of Harpers Ferry will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10; ARC 0111C, IAB 5/2/12, effective 4/13/12]

571—40.28(462A) Black Hawk Lake, Sac County—zoned areas.

40.28(1) No motorboat shall be operated at a speed greater than 5 miles per hour within the zoned area marked by the regulatory buoys. The zoned area shall be the area commonly known as Town Bay on the northwest corner of Black Hawk Lake in Sac County.

40.28(2) Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.29(462A) Speed and other restrictions on Brown's Lake, Woodbury County. All vessels shall be operated at a speed not greater than 5 miles per hour within the two zoned areas designated by regulatory buoys or other approved uniform waterway markers.

40.29(1) Zone 1. Zone 1 shall extend 570 yards from the boat ramp east to the regulatory buoys and 150 yards west from the boat ramp.

40.29(2) Zone 2. Zone 2 shall begin at the regulatory buoys located at the 24-inch steel pipe and shall extend west.

40.29(3) Swimming. Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.30(462A) Speed and other restrictions on Snyder Bend Lake, Woodbury County. All vessels shall be operated at a speed not greater than 5 miles per hour within the zoned area 400 yards from the boat ramp south to the regulatory sign and buoys.

Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.31(462A) Speed restrictions on East Okoboji and West Okoboji Lakes in Dickinson County. No motorboat shall be operated at a speed greater than 5 miles per hour within the three zoned areas designated by regulatory buoys on East Okoboji and West Okoboji Lakes in Dickinson County.

40.31(1) Zone 1. Zone 1 shall be a line from the east side of Givens Point to the south end of Arnolds Park City Beach on West Okoboji. Also, a line 150 yards east from the north end of the railroad trestle bridge at Clair Wilson State Park south to the shoreline of East Okoboji.

40.31(2) Zone 2. Zone 2 shall be the area which is 300 feet north of the area commonly known as the Narrows on East Okoboji and 200 feet south of the area commonly known as the Narrows on East Okoboji.

40.31(3) Zone 3. Zone 3 shall be the area 50 feet east of the bridge between East Okoboji and Upper Gar on the East Okoboji side running in a northwesterly direction toward the end of the island from Gingles Point then west toward the shoreline.

40.31(4) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.31(5) The following areas are zoned 5 miles per hour on West Okoboji.

a. Zone 1. Zone 1 shall be the area commonly known as Okoboji Harbor at the northwest corner of West Okoboji.

b. Zone 2. Zone 2 shall be the area commonly known as the canals in the city of Wahpeton including Turtle Lake.

c. Zone 3. Zone 3 shall be the area commonly known as Lazy Lagoon located in the Triboji Area on West Okoboji.

d. Zone 4. Zone 4 shall be the area commonly known as Little Millers Bay. The zone shall start at Pinkies Point and extend southeasterly (160 degrees) approximately 370 yards until bisecting the southern shoreline of Little Millers Bay.

e. Zone 5. Zone 5 shall be the area commonly known as Little Emmerson Bay. The zone shall start at Breezy Point and extend southwesterly (235 degrees) approximately 330 yards until bisecting the west shoreline of Little Emmerson Bay.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.32(462A) Spirit Lake, Dickinson County—zoned areas.

40.32(1) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.32(2) The following areas are zoned 5 miles per hour on Spirit Lake, Dickinson County:

a. Zone 1 shall be the area commonly known as Templar Park Lagoon located midlake on the west shore of Spirit Lake.

b. Reserved.

571—40.33(462A) Speed restrictions on the Mississippi River, Jackson County, at Spruce Creek County Park. No motorboat shall operate at a speed to exceed 5 miles per hour within the area designated by buoys or other approved uniform waterway markers, beginning at the entrance of Spruce Creek harbor and extending southeast 550 feet and extending east 150 feet from shore. The Jackson County conservation board will designate the speed zone with uniform waterway markers (buoys) approved by the natural resource commission.

571—40.34(462A) Speed restrictions on the Mississippi River, Jackson County, at the city of Sabula. No motorboat shall operate at a speed to exceed five miles per hour within the four zoned areas designated by buoys or other approved uniform waterway markers.

40.34(1) Zone 1. Zone 1 shall extend 200 feet from shore and begin at a point 250 feet upstream of the north Sabula city boat ramp and ending at a point downstream where Bank Street intersects the river bank.

40.34(2) Zone 2. Zone 2 shall extend 200 feet from shore and extend 100 feet upstream and 100 feet downstream from the entrance to the Island City Harbor.

40.34(3) Zone 3. Zone 3 shall extend 200 feet into South Sabula Lake from the county boat ramp and 100 feet to the west of the ramp and 600 feet to the east of the ramp.

40.34(4) Zone 4. Zone 4 shall extend 200 feet in all directions beginning at the center of the “cut” into Lower Sabula Lake.

The city of Sabula shall designate the speed zones with uniform waterway markers (buoys) approved by the natural resource commission.

571—40.35(462A) Speed restrictions on the Greene Impoundment of the Shell Rock River. No motorboat shall be operated at a speed exceeding five miles per hour in the two zoned areas of the Greene Impoundment designated by buoys or other approved uniform waterway markers. The first zoned area extends from the dam in the city of Greene, upstream approximately one-quarter mile to the north boundary of the city park in which the lower boat ramp is located. The second zoned area extends from the county bridge over the Shell Rock River on the north side of section 28 of Union Township in Floyd County, downstream approximately one-quarter mile to the south boundary of Gates Bridge County Park. The city of Greene and Floyd County shall designate their respective speed zones with uniform waterway markers (buoys) approved by the natural resource commission.

571—40.36(462A) Zoning of the Iowa River, Iowa Falls, Hardin County.

40.36(1) All vessels operated in a designated zone between the River Street Bridge and the dock at Dougan’s Landing shall be operated at a speed not greater than 5 miles per hour.

40.36(2) The city of Iowa Falls shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.37(462A) Zoning of Crystal Lake. No motorboat shall be operated at a speed greater than 5 miles per hour within the 25-acre zoned area designated by regulatory buoys on Crystal Lake in Hancock County.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.38(462A) Five Island Lake, Palo Alto County.

40.38(1) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.38(2) Reserved.

571—40.39(462A) Lost Island Lake, Palo Alto and Clay Counties.

40.39(1) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.39(2) Reserved.

571—40.40(462A) Ingham Lake, Emmet County.

40.40(1) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.40(2) Reserved.

571—40.41(462A) Storm Lake, Buena Vista County.

40.41(1) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.41(2) Reserved.

571—40.42(462A) Raccoon River Regional Park Lake, Polk County.

40.42(1) All vessels shall be operated at a speed not greater than 5 miles per hour.

40.42(2) A 40-acre body of water located in the southeast corner, and separate from the main lake, shall be designated for nonmotorized and electric motors only. The city of West Des Moines will designate the area with regulatory buoys and signs.

40.42(3) Areas may be specifically designated for swimming by the use of regulatory buoys.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.43(462A) Zoning of the Mississippi River, Bellevue, Jackson County.

40.43(1) All vessels shall be operated at a speed not greater than 5 miles per hour within the area designated by buoys or other approved uniform waterway markers beginning at the mouth of Mill Creek and extending upstream 900 feet, and extending 200 feet perpendicular from shore. The area shall be designated by a minimum of four approved buoys to be uniformly placed along the 900-foot length of the zone parallel to the shore.

40.43(2) The city of Bellevue will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.44(462A) Three Mile Lake, Union County—watercraft use. Motorboats of outboard or inboard-outdrive type shall be permitted on Three Mile Lake. The following rules shall govern vessel operation on Three Mile Lake in Union County.

40.44(1) All vessels shall be operated at a speed not greater than 5 miles per hour when within 50 feet of another vessel which is not underway or is operating at a speed not greater than 5 miles per hour.

40.44(2) Zoned areas.

a. No vessel, except authorized emergency vessels, shall be permitted in areas specifically designated for swimming and wading which are plainly marked by use of regulatory buoys in accordance with Iowa Administrative Code 571—Chapter 41. The Union County conservation board shall designate and maintain a swimming area(s) by the use of regulatory buoys approved by the natural resource commission.

b. No motorboats, except authorized emergency vessels, shall be operated in marked bay areas at a speed greater than the limit designated by buoys or signs marking said bay. No motorboats, except authorized emergency vessels, shall be operated other than at a speed not greater than 5 miles per hour above a line of buoys placed across the lake at the point where County Road H33 intersects the lake. All buoys or signs shall be in accordance with 571—Chapter 41.

c. No motorboats, except authorized emergency vessels, shall be operated in restricted speed areas between the nearest shore and a line designated by regulatory buoys or signs at a speed greater than the limit designated on the buoys or signs marking the area. Such zoned areas shall be not less than 50 feet nor more than 400 feet from shore. Said buoys or signs shall be in accordance with 571—Chapter 41.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.45(462A) Zoning of the Cedar River.

40.45(1) *Nashua, Chickasaw County.* All vessels operated in a designated zone extending east 150 feet from the intersection of Wabash Street and Charles City Road and north 380 feet shall be operated at a speed not greater than 5 miles per hour. The city of Nashua shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

40.45(2) *Nashua, Chickasaw County.* All vessels operated in a designated zone extending north 131 feet from the intersection of Wabash Street and the north entrance to Cedar View Circle and east 80 feet and west 80 feet from this point along the shoreline and extending 110 feet north into the lake shall be operated at a speed not greater than 5 miles per hour. The city of Nashua shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

40.45(3) *Charles City, Floyd County.* All vessels operated in a designated zone extending 300 feet upstream from the upper dam shall be operated at a speed not greater than five miles per hour. The city of Charles City shall designate and maintain the five miles per hour speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.46(462A) Zoning of Carter Lake, Pottawattamie County.

40.46(1) All vessels operated in a designated zone known as Shoal Pointe Canal shall be operated at a speed not greater than 5 miles per hour.

40.46(2) The city of Carter Lake shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.47(462A) Zoning of the Mississippi River, McGregor, Clayton County.

40.47(1) All vessels, except commercial barge traffic, shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 634 and 633.4 and designated by buoys or other approved uniform waterway markers.

40.47(2) The city of McGregor will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.48(462A) Zoning of the Mississippi River, Marquette, Clayton County.

40.48(1) All vessels, except commercial barge traffic, shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 634.5 and 634.9 and designated by buoys or other approved uniform waterway markers.

40.48(2) The city of Marquette will designate and maintain the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.49(462A) Zoning of Green Island, Jackson County. All motorboats except authorized emergency vessels shall be operated at a speed no greater than 5 miles per hour year around on boat channels adjacent to the interior channel 4 levee at the Green Island State Wildlife area. Both channels begin at the Green Island county road parking lot and proceed north 7920 feet along each side of the channel 4 levee to an intersection with the Snag Slough complex.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.50(462A) Mooring of vessels on riparian property of the state of Iowa. Where the state of Iowa owns riparian property adjacent to sovereign land or water, mooring of vessels is prohibited between sunset and sunrise on those riparian or sovereign lands or waters where posted by either official buoys or official signs of the department of natural resources.

571—40.51(462A) Little River Lake, Decatur County. Motorboats of outboard or inboard-outdrive type shall be permitted on Little River Lake. Vessels operating within a designated area beginning at the dam and extending north approximately to the mouth of “Bait Shop Bay” shall be operated at a speed no greater than 5 miles per hour. The Decatur County conservation board shall designate the speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.52(462A) Zoning of the Mississippi River, Johnson Slough, Clayton County. All vessels shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 627

and 629.8, in a backwater known as Johnson Slough and designated by marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.53(462A) Zoning of the Mississippi River, Mud Lake, Dubuque County. All vessels shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 587.6 to 589.3, in a backwater known as Mud Lake and designated by marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.54(462A) Nighttime speed limit, Dickinson County. No vessels, except authorized emergency vessels, shall be operated at speeds greater than 25 miles per hour at any time between one-half hour after sunset and sunrise on all lakes located in Dickinson County.

571—40.55(462A) Zoning of Clear Lake, Cerro Gordo County.

40.55(1) Areas may be specifically designated for swimming with the use of regulatory buoys.

40.55(2) Areas within close proximity of dredging operations may be designated as areas where the speed of vessels is restricted to not greater than 5 miles per hour.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.56(462A) Zoning of Mississippi River, Des Moines County, city of Burlington. All vessels shall be operated at a speed no greater than five miles per hour within the area designated by marker buoys or other approved uniform waterway markers beginning at the north city boat ramp and public dock and extending downstream to the south city boat ramp and public dock. The zoned area shall extend no farther than 150 feet from the shore and approximately 150 feet west of the west edge of the barge channel. The city of Burlington shall designate the five-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 7532B, IAB 1/28/09, effective 3/6/09]

571—40.57(462A) Zoning of Catfish Creek, Mines of Spain State Recreation Area, Dubuque County. All vessels shall be operated at a speed not greater than 5 miles per hour within the area beginning at the mouth of Catfish Creek and extending upstream to the confluence of Catfish Creek and Granger Creek and designated by uniform marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.58(462A) Zoning of Lake Cornelia, Wright County. All vessels shall be operated at a speed not greater than 5 miles per hour in the boat harbor and at the boat harbor entrance within the zoned area extending 300 feet from two points on shore and 100 feet in width, equidistant from either side of the harbor entrance. The Wright County conservation board shall designate the boat harbor entrance and the public swimming area with uniform marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.59(462A) Zoning of lakes in Dickinson County. All vessels shall be operated at a speed not greater than 5 miles per hour within 300 feet of shore on all lakes in Dickinson County.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.60(462A) Zoning of the Mississippi River, Clayton, Clayton County.

40.60(1) All vessels, except commercial barge traffic, shall be operated at a speed no greater than 5 miles per hour within an area extending 150 feet from shore and beginning at a point 1,012 feet north of Mississippi River Day Marker 624.7R and extending south to a point 1,012 feet south of the same marker (624.7R).

40.60(2) The city of Clayton shall designate and maintain the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 1644C, IAB 10/1/14, effective 11/5/14]

These rules are intended to implement the provisions of Iowa Code sections 462A.17, 462A.26, and 462A.31.

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[◇] Two or more ARCs

PUBLIC EMPLOYMENT RELATIONS BOARD[621]

[Prior to 11/5/86, Public Employment Relations Board [660]]

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CHAPTER 1 GENERAL PROVISIONS

621—1.1(20) Construction and severability. These rules shall be liberally construed to effectuate the purposes and provisions of the public employment relations Act. If any provisions of these rules are held to be invalid, it shall not be construed to invalidate any of the other provisions of these rules.

621—1.2(20) General agency description. The purpose of the public employment relations board established by the Public Employment Relations Act is to implement the provisions of the Act and adjudicate and conciliate employment related cases involving the state of Iowa and other public employers and employee organizations. For these purposes the powers and duties of the board include, but are not limited to, the following:

Determining appropriate bargaining units and conducting representation elections.

Adjudicating prohibited practice complaints and fashioning appropriate remedial relief for violations of the Act.

Adjudicating and serving as arbitrators regarding state merit system grievances and grievances arising under collective bargaining agreements between public employers and certified employee organizations.

Providing mediators and arbitrators to resolve impasses in negotiations.

Collecting and disseminating information concerning the wages, hours, and other conditions of employment of public employees.

Preparing legal briefs and presenting oral arguments in the district courts, the court of appeals and the supreme court in cases affecting the board.

[ARC 8953B, IAB 7/28/10, effective 9/1/10]

621—1.3(20) General course and method of operation. Upon receipt of a petition or complaint, the board may assign an administrative law judge to process the case. The board may determine that the petition or complaint is without basis and dismiss it without further proceedings. Petitions and complaints not dismissed are assigned for a hearing before either an administrative law judge or the board, unless the procedures for informal settlement described in these rules are followed. The administrative law judge or the board will conduct a hearing on the complaint or petition and issue a decision and order. The decisions of administrative law judges are appealable to the board, and final orders and decisions of the board are appealable to the district court under the Iowa administrative procedure Act.

621—1.4(20) Method of obtaining information and making submissions or requests. Any person may obtain information from, make submission to, or make a request of the board by writing to Chairperson, Iowa Public Employment Relations Board, 510 East 12th Street, Suite 1B, Des Moines, Iowa 50319.

621—1.5(20) Petition for rule making. Any person may file a petition with the board for the adoption, amendment or repeal of a rule. Such petition shall be in writing and shall include:

1.5(1) The name and address of the person requesting the adoption, amendment or repeal of the rule.

1.5(2) A statement of the specific rule-making action sought by the petitioner including the text or a summary of the contents of the proposed rule or amendment to a rule and, if it is a petition to amend or repeal a rule, a citation to and the relevant language of the particular portion or portions of the rule proposed to be amended or repealed.

1.5(3) A brief summary of petitioner's arguments in support of the action urged in the petition.

1.5(4) A brief summary of any data supporting the action urged in the petition.

1.5(5) The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by or interested in the proposed action which is the subject of the petition. Within 60 days after the filing of a petition, the board shall either deny the petition in writing, stating its reasons for the denial, or initiate rule-making proceedings in accordance with Iowa Code chapter 17A.

621—1.6(20) Definitions.

1.6(1) “*Act*” as used in these rules shall mean the public employment relations Act, Iowa Code chapter 20.

1.6(2) “*Board*” as used in these rules shall mean the public employment relations board. No official board action may be taken without the concurrence of at least two members of the board; provided, however, that when for compelling reasons only two members hear an appeal of a proposed decision in a contested case and the two members do not concur, the result shall be affirmation of the proposed decision. The board, in its discretion, may delegate to board employees duties which the Act does not specifically require be performed by the board.

1.6(3) *Petitioner—complainant—respondent—intervenor:*

- a. “*Petitioner*” means the party filing a petition under Iowa Code section 20.13 or 20.14.
- b. “*Complainant*” means the party filing a complaint under Iowa Code section 20.11, alleging the commission of a prohibited practice.
- c. “*Respondent*” means the party accused of committing a prohibited practice.
- d. “*Intervenor*” means a party who voluntarily interposes in a proceeding with the approval of the board or administrative law judge.

1.6(4) “*Party*” as used in these rules shall mean any person, employee organization or public employer who has filed a petition or complaint under the Act or these rules; who has been named as a party in a complaint, petition or other matter under these rules; or whose motion to intervene has been granted by the board.

1.6(5) “*Impasse item*” means any term which was a subject of negotiations and proposed to be included in a collective bargaining agreement upon which the parties have failed to reach agreement in the course of negotiations, except as provided for in 621—6.1(20). Failure of the parties to agree upon impasse procedures shall not constitute an impasse item or compel implementation of impasse procedures.

1.6(6) “*Impasse procedures*” means either the procedures set forth in Iowa Code sections 20.20 and 20.22 or any procedures agreed upon by the parties pursuant to Iowa Code section 20.19 which are designed to result in a binding collective bargaining agreement.

1.6(7) “*Contested case*” means a proceeding defined by Iowa Code section 17A.2(5) and includes any matter defined as a no factual dispute contested case under 1998 Iowa Acts, chapter 1202, section 14.

1.6(8) “*Adjudicatory proceeding*” means a contested case, a proceeding that may culminate in a contested case, a petition for declaratory order, a petition for expedited resolution of a negotiability dispute, or any other proceeding which may require the board or its designee to issue a decision, order, or ruling.

1.6(9) “*Agency*” as used in these rules means the public employment relations board and the board’s employees.

1.6(10) “*Confidential information*” means information excluded from public access by federal or state law or administrative rule, court rule, court or administrative order, or case law.

1.6(11) “*Protected information*” means personal information, the nature of which warrants protection from unlimited public access, including:

- a. Social security numbers.
- b. Financial account numbers.
- c. Dates of birth.
- d. Names of minor children.
- e. Individual taxpayer identification numbers.
- f. Personal identification numbers.
- g. Other unique identifying numbers.

[ARC 8953B, IAB 7/28/10, effective 9/1/10; ARC 1583C, IAB 8/20/14, effective 9/24/14]

621—1.7(20) Computation of time. Time periods established by these rules shall be computed pursuant to Iowa Code section 4.1(34).

621—1.8(20,279) Fees of neutrals. Rescinded ARC 1642C, IAB 10/1/14, effective 11/5/14.

621—1.9(17A,20) Waiver or variance of rules.

1.9(1) Definitions.

a. “Waiver or variance” as used in this rule means action by the board which suspends, in whole or in part, the requirements or provisions of a rule as applied to an identified individual or entity on the basis of the particular circumstances of that individual or entity. The term “waiver” as used herein shall include both a waiver and a variance.

b. “Provision of law” as used in this rule means a provision of law as defined by Iowa Code section 17A.2(10).

1.9(2) Purpose and scope. This rule creates a generally applicable process and specifies applicable criteria for granting individual waivers from rules adopted by the board in situations in which no other specifically applicable provision of law provides for waiver. To the extent another more specific provision of law governs the issuance of a waiver from a particular rule, the more specific waiver provision shall supersede this rule with respect to any waiver of that rule.

1.9(3) When waiver unavailable. No waiver may be granted pursuant to this rule unless the board has jurisdiction over the rule to which the waiver request applies and the requested waiver is consistent with any applicable statute, constitutional provision or other provision of law. The board may not waive requirements created or duties imposed by statute.

1.9(4) Criteria for waiver. In response to a petition filed in accordance with this rule the board may, in its sole discretion, issue an order waiving the requirements of a rule or rules if the board finds, based on clear and convincing evidence, all of the following:

- a.* The application of the rule would pose an undue hardship on the entity or individual for whom the waiver is requested;
- b.* The waiver of the rule in the particular case would not prejudice the substantial legal rights of any individual or entity;
- c.* The provisions of the rule or rules to which the waiver request applies are not specifically mandated by statute or other provision of law; and
- d.* Substantially equal protection of public health, safety and welfare will be afforded by a means other than that prescribed in the particular rule or rules to which the waiver request applies.

1.9(5) Filing of petition. All petitions requesting a waiver must be filed personally or by mail with the board at its offices at 510 East 12th Street, Suite 1B, Des Moines, Iowa 50319. If the petition relates to a pending contested case proceeding or a proceeding pending before the agency which could culminate in a contested case proceeding, the petition shall be filed in and bear the caption of that proceeding. The board shall acknowledge the filing of a petition by providing the petitioner with a file-stamped copy.

1.9(6) Content of petition. A petition requesting a waiver shall be in writing and shall include the following information where applicable and known to the petitioner:

- a.* The name, address and telephone number of the individual or entity requesting the waiver and of the individual’s or entity’s authorized representative, if any.
- b.* A citation of the specific rules, rule or part thereof from which a waiver is requested.
- c.* A description of the precise scope and duration of the waiver requested.
- d.* A statement of the relevant facts the petitioner believes would justify a waiver under each of the criteria specified in subrule 1.9(4), together with an affirmation signed by the petitioner attesting to the accuracy of the facts asserted in the petition.
- e.* A history of any prior contacts within the last five years by or between the board or its representatives and the petitioner concerning the matter which would be affected by the requested waiver, including references to all past or pending agency proceedings relating to the matter.
- f.* Any information known to the petitioner regarding the board’s treatment of waiver requests by similarly situated individuals or entities under similar circumstances.
- g.* The name, address and telephone number of any other governmental agency or entity which also regulates the activity in question or which might be affected by the granting of the requested waiver.

h. The name, address and telephone number of each individual or entity, public or private, which might be adversely affected by the granting of the requested waiver.

i. The name, address and telephone number of each individual with knowledge of the relevant facts relating to the requested waiver.

j. Signed releases of information authorizing individuals with knowledge of relevant facts relating to the requested waiver to furnish the board with such information.

1.9(7) *Timing and effect of petition.* If the petition seeks waiver of a time requirement specified by a rule, it must be filed as soon as possible but, in every case, before the expiration of the time period sought to be waived. The filing of a petition does not itself stay the operation of any agency rule, including the rule which is the subject of the petition.

1.9(8) *Service of petition.* The petitioner shall, within ten days of the filing of the petition, serve a copy thereof, in accordance with the provisions of rule 621—2.15(20), upon all entities or individuals named in or potentially affected by the petition or to whom notice is required by any provision of law and shall file proof of such service with the board. The board may also give notice of the petition to other individuals or entities.

1.9(9) *Additional information.* Prior to issuing an order granting or denying a waiver, the board may request additional information from the petitioner or other individuals or entities relating to the petition and the surrounding circumstances. Unless the petition is filed in a pending contested case proceeding, the board may, on its own motion or at the request of the petitioner or other interested individual or entity, schedule and conduct a telephonic or in-person meeting with the petitioner to discuss the request and surrounding circumstances and may include other interested individuals or entities.

1.9(10) *Procedure in contested cases.* The provisions of Iowa Code sections 17A.10 through 17A.18A regarding contested case hearings shall apply to petitions for a waiver which are filed in a pending contested case proceeding, but shall otherwise apply to proceedings on such petitions only when required by statute or when the board so provides by rule or order.

1.9(11) *Board discretion.* The final decision to grant or deny a waiver is vested in the board and shall be made wholly at its discretion following its consideration of all relevant factors, including the unique, individual circumstances set out in the petition. When the rule to which the petition relates establishes administrative deadlines, the board's consideration shall include a balancing of the individual circumstances of the petitioner with the board's policy favoring the uniform treatment of all similarly situated individuals or entities.

1.9(12) *Burden of persuasion.* The petitioner bears the burden of demonstrating, by clear and convincing evidence, that the board should exercise its discretion to grant a waiver pursuant to this rule.

1.9(13) *Ruling on petition.* The board shall issue a written ruling which includes an order granting or denying the requested waiver. The ruling shall contain a statement of the relevant facts and reasons upon which the order is based and a description of the precise scope and duration of any waiver granted.

1.9(14) *Time for ruling.* The board will issue its ruling as soon as practicable, but shall do so within 120 days of its receipt of the petition unless the petitioner agrees to a later date. However, if the petition was filed in a contested case proceeding or in a pending agency proceeding which has subsequently become a contested case proceeding, ruling on the petition may be withheld until the issuance of the final agency decision in that case.

1.9(15) *Deemed denial of petition.* Failure by the board to grant or deny a petition within the time required by subrule 1.9(14) shall be deemed a denial of the petition. However, notwithstanding such deemed denial, the board shall remain responsible for issuing a ruling pursuant to subrule 1.9(13).

1.9(16) *Scope and conditions of waiver.* Any waiver granted shall provide the narrowest exception possible to the provisions of the rule being waived. The board may include as a part of its granting of a waiver such conditions as it finds desirable to protect the public welfare or to achieve through alternative means the objectives of the particular rules, rule or part thereof being waived. A waiver shall not be permanent unless the petitioner has shown that a temporary waiver would be impracticable. Should a temporary waiver be granted, there is no automatic right to its renewal. A waiver may be renewed, in the sole discretion of the board, upon the filing and service of a petition for renewal which complies with the provisions of this rule and a finding by the board that grounds for a waiver continue to exist.

1.9(17) *Service of ruling.* Within seven days of its issuance, the board's ruling on the petition shall be served by the board by ordinary mail upon the petitioner, any entity or individual to whom the ruling pertains and any other individuals or entities entitled to notice pursuant to any other provision of law.

1.9(18) *Indexing and public availability.* The board shall maintain a record of all rulings on petitions filed pursuant to this rule, which shall be indexed and available for public inspection at the board's offices subject to the provisions of Iowa Code section 17A.3. Because petitions and rulings may contain information which the board is authorized or required to keep confidential, the board may redact such confidential information from such petitions and rulings prior to public inspection.

1.9(19) *Effect of waiver.* Any waiver granted by the board shall constitute a defense, within the terms and the specific facts set forth therein, for the entity or individual to whom the waiver pertains in any proceeding in which the rule in question is sought to be invoked. The waiver is effective only as to the entity or individual to whom it was granted, is not assignable and does not inure to the benefit of the individual's or entity's successor(s) in interest.

1.9(20) *Cancellation of waiver.* A waiver granted pursuant to this rule may be canceled, withdrawn or modified if, after appropriate notice and hearing, the board finds:

a. An entity or individual who requested or was the subject of the waiver withheld from or knowingly misrepresented to the board material facts relevant to the propriety or desirability of the waiver; or

b. The alternative means for ensuring that the public welfare will be adequately protected and the purposes of the rule or set of rules waived will be adequately served after issuance of the waiver have been demonstrated to be insufficient, or

c. The subject of the waiver has failed to comply with all of the conditions specified in the order granting the waiver.

1.9(21) *Violations.* A violation of a condition specified in an order granting a waiver shall be treated as a violation of the particular rules, rule or portion thereof waived by the board. As a result, the recipient of a waiver under this rule who violates such a condition may be subject to the same remedies or penalties as an entity or individual who violates the rules, rule or portion thereof waived by the board.

1.9(22) *Appeals.* Any intra-agency or judicial review of rulings granting or denying waivers pursuant to this rule shall be in accordance with other applicable board rules and Iowa Code chapter 17A.

1.9(23) *Summary reports.* All orders granting or denying a waiver pursuant to this rule shall be summarized in semiannual reports which comply with and are distributed pursuant to the requirements of Iowa Code section 17A.9A.

621—1.10(20) Agency record and files.

1.10(1) *Agency record.* The official agency record for all adjudicatory proceedings includes the following:

- a.* Electronic files maintained in the agency's electronic document management system;
- b.* Paper documents maintained by the agency in paper form when permitted by the board's order; and
- c.* Exhibits and other materials filed with or delivered to and maintained by the agency as part of the case file.

1.10(2) *Paper case files.* Except as otherwise provided in the agency's rules or directed by the board, the agency will not maintain paper case files in adjudicatory proceedings filed on or after January 1, 2015. [ARC 1583C, IAB 8/20/14, effective 9/24/14]

These rules are intended to implement Iowa Code section 17A.9A and chapters 20 and 279.

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[Filed ARC 1583C (Notice ARC 1507C, IAB 6/25/14), IAB 8/20/14, effective 9/24/14]
[Filed ARC 1642C (Notice ARC 1570C, IAB 8/6/14), IAB 10/1/14, effective 11/5/14]

CHAPTER 13 MEDIATORS

621—13.1(20) Scope and authority. This chapter applies to all mediators listed on the agency's mediator list and to all persons applying for inclusion on the list.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.2(20) Definitions.

"Ad hoc mediator" means a person included on the list who enters into an independent contractor agreement with the agency to provide mediation to parties requesting impasse services pursuant to Iowa Code section 20.20.

"Advocate" means a person who represents employers, employee organizations, or individuals or entities in labor relations or employment relations matters, including but not limited to the subjects of union representation and recognition matters, negotiations, mediation, arbitration, unfair or prohibited labor practices, equal employment opportunity, and other areas generally recognized as constituting labor or employment relations. "Advocate" includes representatives of employers or employees in individual cases or controversies involving workers' compensation, occupational health or safety, minimum wage, or other labor standards matters. "Advocate" also includes persons directly or indirectly associated with an advocate in a business or professional relationship as, for example, partners or employees of a law firm.

"FMCS" means the Federal Mediation and Conciliation Service.

"Qualified-mediator list" or *"list"* means the agency-maintained list of mediators who have met the criteria set forth in this chapter.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.3(20) List and status of members.

13.3(1) *The list.* The agency shall maintain a list of mediators who meet the criteria for listing contained in rule 621—13.4(20) and who remain in good standing.

13.3(2) *Adherence to standards and requirements.* Persons included on the list shall comply with the agency's administrative rules pertaining to mediation. Mediators shall conform to the ethical standards and procedures set forth in the current Code of Professional Conduct for Labor Mediators, as approved and published by the Association of Labor Relations Agencies, and chapter 11 of the Iowa Court Rules. When in conflict, the Code of Professional Conduct for Labor Mediators shall take precedence over the Iowa Court Rules.

13.3(3) *Status of FMCS and ad hoc mediators.* Ad hoc mediators and mediators employed by FMCS are not employees of the state of Iowa.

13.3(4) *Rights of persons on the list.* Placement on the list shall be at the sole discretion of the board.

13.3(5) *Assignments.* The agency has sole discretion to make and modify mediation assignments.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.4(20) Mediator listing.

13.4(1) *Categories of mediators.* The list shall consist of three categories of mediators:

- a. The agency's professional staff;
- b. Mediators employed by FMCS; and
- c. Ad hoc mediators.

13.4(2) *Application procedures for ad hoc mediators.* Persons seeking to be included on the list must complete and submit an application to the agency. Applicants shall submit at least two professional references, preferably one reference from management and one reference from labor. The board will review the application under the criteria set forth in this rule and shall make a final decision as to whether an applicant may be placed on the list. Satisfactorily meeting all criteria does not entitle an applicant to inclusion on the list. Each applicant shall be notified in writing of the board's decision.

13.4(3) *Knowledge and abilities.* Applicants must establish requisite knowledge and abilities as follows:

- a. Good verbal and written communication skills;
- b. The ability and willingness to travel throughout Iowa and to work prolonged and unusual hours;
- c. Knowledge of Iowa Code chapter 20, the agency's administrative rules, and principles and practices of contracts, public finance, and labor relations; and
- d. The ability and willingness to conduct a mediation in a fair and impartial manner.

13.4(4) Experience. Applicants must demonstrate requisite experience in labor relations or mediation in one of the following ways:

- a. At least three years of collective bargaining experience in the public or private sector;
- b. At least three years of actual mediation experience;
- c. At least five years of other relevant experience in labor-related fields including but not limited to human resource management, industrial relations, and labor unionism;
- d. A law degree or a master's or equivalent degree in industrial or labor relations or alternative dispute resolution; or
- e. Experience that is a combination of that described in paragraphs "a" through "d" of this subrule.

13.4(5) Geographical location. Preference will be given to applicants residing in or near areas of the state where few other listed mediators reside.

13.4(6) Training.

- a. Prior to inclusion on the list, an applicant must complete the following training:
 - (1) Formal training provided by the agency; and
 - (2) Mentorship in at least two disputes with an experienced, listed mediator. The board may require additional mentoring if deemed necessary.
- b. Training requirements may be waived by the board for applicants with prior public sector mediation experience.

13.4(7) Conflict of interest. Prior to inclusion on the list, all applicants must disclose potential conflicts of interest as described in subrule 13.6(1).

13.4(8) Exemption. Persons on the agency's professional staff and mediators employed by FMCS shall not be required to submit an application for listing and shall be deemed as meeting all criteria set forth in subrules 13.4(3) through 13.4(6) throughout the duration of their employment with the agency or FMCS.

13.4(9) Grandfather clause. Any person listed prior to November 5, 2014, shall be deemed as meeting all criteria set forth in subrules 13.4(3), 13.4(4) and 13.4(6).

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.5(20) Independent contractor agreement. An ad hoc mediator must enter into an independent contractor agreement with the agency prior to receiving mediation assignments. The independent contractor agreement between the ad hoc mediator and the agency shall establish the hourly rate, reimbursable fees and expenses, duration, and other terms and conditions.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.6(20) Conflict of interest.

13.6(1) Conflict of interest. The board shall determine whether a person has a conflict of interest which may require denial of an application or removal from the list or from individual assignments. A conflict of interest arises where:

- a. A mediator is or has been an employee or advocate for a party to the mediation within the prior two years; or
- b. A mediator's immediate family member, or any other person with whom the mediator has close, personal ties, is an interested party in the outcome of the mediation; or
- c. Any other matter that may create an appearance of bias, lack of impartiality, or interest in the proceedings to which the mediator may be or has been assigned.

13.6(2) Duty to disclose. A person applying for inclusion on the list or a person included on the list has a continuing duty to disclose to the board in writing any potential or actual conflicts of interest as described in subrule 13.6(1).

13.6(3) Disclosure. The board may require a mediator to disclose certain matters to the parties of a mediation prior to its commencement. If either party objects to proceeding to mediation with that mediator, the board may assign a different mediator.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.7(20) Confidentiality.

13.7(1) Exemption from open meetings law. In accordance with Iowa Code section 20.17(3), communications between the parties and the mediator during the course of a mediation shall be exempt from the provisions of Iowa Code chapter 21.

13.7(2) Mediator privilege. In accordance with Iowa Code section 20.31(2), a mediator shall not testify in judicial, administrative, or grievance proceedings regarding any matters occurring in the course of a mediation, including any verbal or written communication or behavior, other than facts relating exclusively to the timing or scheduling of mediation. A mediator shall not produce or disclose any documents, including notes, memoranda, or other work product, relating to mediation, other than documents relating exclusively to the timing or scheduling of mediation.

13.7(3) Exception. Subrule 13.7(2) shall not apply in any of the following circumstances:

- a. The testimony, production, or disclosure is required by statute;
- b. The testimony, production, or disclosure provides evidence of an ongoing or future criminal activity; or
- c. The testimony, production, or disclosure provides evidence of child abuse as defined in Iowa Code section 232.68(2).

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.8(20) Complaints. Any affected person or party shall direct a complaint against a mediator who is on the list to the board. The board will consider the complaint and other relevant information and take such action it deems appropriate.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—13.9(20) Inactive status. A member of the list who continues to meet the criteria for inclusion on the list shall inform the agency if the member is unavailable for assignment on a temporary basis because of illness, vacation, schedule, or other reasons. That member will not receive assignments during the period in which the member is unavailable.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

These rules are intended to implement Iowa Code sections 20.1, 20.6 and 20.20.

[Filed ARC 1642C (Notice ARC 1570C, IAB 8/6/14), IAB 10/1/14, effective 11/5/14]

CHAPTER 14 ARBITRATORS

621—14.1(20) Scope. This chapter applies to all arbitrators listed on the agency's qualified-arbitrator roster and to all applicants for listing on the roster.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.2(20) Definitions.

"Advocate" means a person who represents employers, employee organizations, or individuals or entities in labor relations or employment relations matters, including but not limited to the subjects of union representation and recognition matters, negotiations, mediation, arbitration, unfair or prohibited labor practices, equal employment opportunity, and other areas generally recognized as constituting labor or employment relations. "Advocate" includes representatives of employers or employees in individual cases or controversies involving workers' compensation, occupational health or safety, minimum wage, or other labor standards matters. "Advocate" also includes persons directly or indirectly associated with an advocate in a business or professional relationship as, for example, partners or employees of a law firm.

"Arbitrator" means a person serving as a neutral decision-maker in interest arbitrations, grievance arbitrations, or teacher termination adjudications.

"Grievance arbitration" means the proceedings on an alleged contract violation as provided in a collective bargaining agreement entered into pursuant to Iowa Code chapter 20.

"Grievance arbitrator" means a person serving as a neutral decision-maker in a grievance arbitration.

"Interest arbitration" means the binding arbitration contemplated by Iowa Code section 20.22 or by an impasse agreement entered into pursuant to Iowa Code section 20.19.

"Interest arbitrator" means a person serving as a neutral decision-maker in an interest arbitration.

"Qualified-arbitrator roster" or "roster" means the agency-maintained list of arbitrators who have met the criteria set forth in this chapter.

"Teacher termination adjudication" means the proceedings contemplated by Iowa Code section 279.17.

"Teacher termination adjudicator" means a person serving as a neutral decision-maker in a teacher termination adjudication.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.3(20) Roster and status of members.

14.3(1) *The roster.* The agency shall maintain a roster of arbitrators who meet the criteria for listing contained in rule 621—14.5(20) and who remain in good standing.

14.3(2) *Adherence to standards and requirements.* Persons listed on the roster shall comply with the agency's administrative rules pertaining to arbitrators. Arbitrators shall conform to the ethical standards and procedures set forth in the current Code of Professional Responsibility for Arbitrators of Labor Management Disputes, as approved and published by the National Academy of Arbitrators, Federal Mediation and Conciliation Service, and the American Arbitration Association.

14.3(3) *Status of arbitrators.* Persons who are listed on the roster are not employees of the state of Iowa. A selected arbitrator's contractual relationship is solely with the parties to the dispute.

14.3(4) *Roster listing fee.* An annual listing fee of \$150 for each roster member is established to maintain the roster. Roster members shall remit payment to the agency by November 1 each year. This fee shall be considered a repayment receipt as defined in Iowa Code section 8.2.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.4(20) Fees of arbitrators. Qualified arbitrators selected from the roster may be compensated by a sum not to exceed \$1,200 per day of service, plus their necessary expenses incurred.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.5(20) Arbitrator roster.

14.5(1) *Categories of arbitrators.* The roster shall consist of three categories of arbitrators:

- a. Interest arbitrators;
- b. Grievance arbitrators; and
- c. Teacher termination adjudicators.

Persons may be listed on the roster in each category in which they meet the criteria.

14.5(2) *Initial application procedures.* Persons seeking to be listed on the roster in one or more categories must complete and submit an application to the board. Applicants shall submit at least one reference from management, one reference from labor, and applicable writing samples. The board will review the application under the criteria, as set forth in subrules 14.5(3), 14.5(4), 14.5(5), and 14.5(6), and shall make a final decision concerning whether an applicant will be listed on the roster and under which category or categories the applicant qualifies. Each applicant shall be notified in writing of the board's decision.

14.5(3) *Knowledge and abilities.* Applicants must establish requisite knowledge and abilities as follows:

- a. For listing on the roster as an interest arbitrator:
 - (1) Good verbal and written communication skills;
 - (2) The ability and willingness to travel throughout Iowa and to work prolonged and unusual hours;
 - (3) Knowledge of Iowa Code chapter 20, the agency's rules, and principles and practices of contracts, public finance, and labor relations; and
 - (4) The ability to conduct evidentiary hearings in a fair and impartial manner, develop an accurate record, and prepare and issue clear, reasoned and timely awards. For purposes of this subparagraph, "timely" means within 15 days after the interest arbitration hearing pursuant to Iowa Code section 20.22(9) or in a time frame established by an impasse agreement entered into pursuant to Iowa Code section 20.19.
- b. For listing on the roster as a grievance arbitrator:
 - (1) Good verbal and written communication skills;
 - (2) The ability and willingness to travel throughout Iowa and to work prolonged and unusual hours;
 - (3) Knowledge of arbitral principles and practices, contracts, and labor relations; and
 - (4) The ability to conduct evidentiary hearings in a fair and impartial manner, develop an accurate record, and prepare and issue clear, reasoned and timely awards. For purposes of this subparagraph, "timely" means within the time frame established by the parties' collective bargaining agreement entered into pursuant to Iowa Code chapter 20.
- c. For listing on the roster as a teacher termination adjudicator:
 - (1) Good verbal and written communication skills;
 - (2) The ability and willingness to travel throughout Iowa and to work prolonged and unusual hours;
 - (3) Knowledge of Iowa Code section 279.17; and
 - (4) The ability to review adjudicatory records developed by another body, hear legal arguments in a fair and impartial manner, and prepare and issue clear, reasoned and timely decisions. For purposes of this subparagraph, "timely" means within 15 days after the teacher termination adjudication hearing pursuant to Iowa Code section 279.17(7).

14.5(4) *Experience.*

a. Applicants must demonstrate requisite experience in labor relations or arbitration in the category in which the applicant seeks listing on the roster in one of the following ways:

- (1) For listing on the roster as an interest arbitrator:
 1. Issuance of at least four fact-finding or interest arbitration decisions or a combination thereof;
 2. At least three years' experience as a mediator in collective bargaining interest disputes, with training and experience in conducting hearings and issuing reasoned awards; or
 3. At least five years' experience in labor relations or labor law, with training and experience in conducting hearings and issuing reasoned awards.
- (2) For listing on the roster as a grievance arbitrator:
 1. Issuance of at least four grievance awards; or

2. At least five years' experience in labor relations or labor law, with training and experience in conducting hearings and issuing reasoned awards.

(3) For listing on the roster as a teacher termination adjudicator:

1. Issuance of at least four decisions rendered in an appellate capacity; or

2. At least five years' experience in the field of education, with training and experience in reviewing adjudicatory records and issuing reasoned decisions.

b. The board may give credit against the years of experience requirement to a candidate who has received a master's or equivalent degree in a related area or who has adjudicatory experience in a field or fields other than labor relations.

14.5(5) Conflict of interest. Prior to inclusion on the roster, all applicants must disclose potential conflicts of interest as described in subrule 14.8(1).

14.5(6) Training. Prior to inclusion on the roster as an interest arbitrator, applicants must complete formal training provided by the agency.

14.5(7) Exemption. Applicants who qualify for and complete the agency's interest arbitrator mentorship program, as outlined in rule 621—14.6(20), shall be exempt from the criteria set forth in subparagraph 14.5(4) "a"(1) and subrule 14.5(6).

14.5(8) Duration of listing. Listing on the roster shall be for a term of three years.

14.5(9) Renewal application.

a. The board shall notify a roster member not less than 120 days before the expiration of the member's three-year term of the procedures necessary to continue inclusion on the roster.

b. A roster member desiring to renew the member's listing must submit a written application to the board not less than 60 days before the expiration of the member's three-year term.

c. When reviewing a renewal application, the board shall consider the following criteria, plus any other relevant information, in determining whether to renew the person's listing:

(1) Demonstration of the requisite knowledge and abilities as listed in subrule 14.5(3);

(2) Acceptability, which may be based on the agency's records that show the number of times the arbitrator's name has been proposed to the parties and the number of times the arbitrator has been selected. Such cases will be reviewed for extenuating circumstances, such as the arbitrator's length of time on the roster or prior history;

(3) Timeliness of decisions;

(4) Feedback from the parties; and

(5) Attendance at agency-sponsored events, including conferences and trainings.

d. Within 60 days of receipt of the completed application, the board shall issue and serve in accordance with 621—subrule 2.15(2) a written decision granting or denying the renewal application.

(1) If renewal is granted, the roster member shall remit payment of the annual listing fee in accordance with subrule 14.3(4).

(2) If renewal is denied, the renewal applicant may request reconsideration of the denial within 14 days of issuance of the denial. The board shall hold a hearing conducted in accordance with 621—Chapter 2 within 60 days of the request for reconsideration and shall issue its final ruling within 30 days of the hearing. Absent a timely request for reconsideration, the board's denial of the renewal application becomes final, and the arbitrator shall be removed from the roster.

14.5(10) Grandfather clause. Any arbitrator listed on the roster prior to November 5, 2014, shall be deemed to meet all criteria set forth in subrules 14.5(3), 14.5(4), and 14.5(6) for up to three years following November 5, 2014. For purposes of renewal, the agency shall divide arbitrators listed on the roster on November 5, 2014, into three groups with staggered renewal dates and will notify the members of each group when their renewal applications are due.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.6(20) Interest arbitrator mentorship program.

14.6(1) Goal. It is a goal of the board to increase the number of Iowa residents qualified to be on the roster. Such increase should provide constituents additional options for hiring arbitrators whose reimbursable expenses, such as for mileage and accommodations, are lower and who are more familiar

with situations facing the parties. The board may suspend the interest arbitrator mentorship program at any time.

14.6(2) *Application procedures.* Persons seeking to participate in the program must complete and submit an application on a form prescribed by the board. The board will review the application and make a final decision whether an applicant qualifies for the program in accordance with subrule 14.6(3). Each applicant shall be notified in writing of the board's decision.

14.6(3) *Qualifications.* To be eligible to participate in the program, an applicant must meet the following qualifications:

- a.* Be a resident of the state of Iowa at the time of application and throughout the duration of the mentorship program and maintain the residency for the first year of listing;
- b.* Have at least five years of collective bargaining experience in the public or private sector as an advocate, mediator, or combination of both;
- c.* Possess good verbal and written communication skills;
- d.* Have the ability and willingness to travel throughout Iowa and to work prolonged and unusual hours; and
- e.* Not have a conflict of interest as described in subrule 14.8(1).

14.6(4) *The program.*

- a.* The program shall consist of the following steps:
 - (1) Formal training by the agency regarding Iowa Code chapter 20, the agency's administrative rules, and how to conduct hearings and write awards;
 - (2) Shadowing an experienced arbitrator listed on the roster in at least two interest arbitrations; and
 - (3) Submission of at least two mock interest arbitration awards that comply with statutory and regulatory requirements. The board may require additional mock awards if deemed necessary.
- b.* Successful completion of the program will result in the participant's inclusion on the roster as an interest arbitrator. Participants must satisfy the criteria for grievance arbitrators and teacher termination adjudicators outlined in subrules 14.5(3) and 14.5(4) prior to inclusion on the roster under those categories.

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.7(20) Biography. Each roster member shall maintain a biography in a form prescribed by the board. The roster member is responsible for ensuring that the biography is accurate and current. The agency bears no responsibility for inaccurate, incomplete, or outdated information in biographies. The member's biography shall contain the following:

1. Name, address, telephone number, and e-mail address;
2. Current and past employment, including the member's representative client base if not readily identifiable;
3. Education history;
4. Per diem rate and other applicable charges or fees;
5. Relevant experience, including but not limited to listing on other arbitrator rosters or memberships/associations; and
6. Potential or actual conflicts of interest as described in subrule 14.8(1).

[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.8(20) Conflict of interest.

14.8(1) *Conflict of interest.* The board shall determine whether a person has a conflict of interest which may require denial of an initial or renewal application or removal from the roster or from individual selections. A conflict of interest arises where:

- a.* An arbitrator is or has been an employee or advocate for a party to the arbitration within the prior two years;
- b.* An arbitrator's immediate family member, or any other person with whom the arbitrator has close, personal ties, is an interested party in the outcome of the arbitration; or
- c.* Any other matter that may create an appearance of bias, lack of impartiality, or interest in the proceedings to which the arbitrator may be or has been selected.

14.8(2) *Duty to disclose.* A person applying for inclusion on the roster or a person listed on the roster has a continuing duty to disclose to the board in writing any potential or actual conflicts of interest as described in subrule 14.8(1).

14.8(3) *Disclosure.* The board may require an arbitrator to disclose certain matters to the parties of an arbitration prior to its commencement. If either party objects to proceeding to arbitration with that arbitrator, the board may require the parties to make an alternate selection.
[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.9(20) Procedures for discipline and removal.

14.9(1) *Grounds.* Probation, suspension, or removal from the roster may be based upon one or a combination of any of the following, including but not limited to:

- a. Failure to comply with statutory provisions, the agency's administrative rules, and agency guidelines and policies;
- b. Delinquency in submitting awards;
- c. Existence of a conflict of interest as described in subrule 14.8(1) that requires exclusion from the roster;
- d. Failure to disclose to the board or the parties any conflict of interest as described in subrule 14.8(1);
- e. Failure to demonstrate the requisite knowledge and abilities listed in subrule 14.5(3);
- f. Any other reason for which the board deems discipline or removal to be in the best interest of the agency, its constituents, or the public at large.

14.9(2) *Automatic removal.* Any roster member who fails to pay the annual listing fee pursuant to subrule 14.3(4) shall be removed from the roster, absent good cause shown for why removal is inappropriate. Any member who fails to submit a renewal application pursuant to paragraph 14.5(9) "b" shall be removed from the roster 30 days after the expiration of the member's term, absent good cause shown for why removal is inappropriate.

14.9(3) *Filing of a complaint.*

a. Any affected person or party may file with the board a complaint against an arbitrator listed on the roster. The board may also file a complaint pursuant to this subrule. Such complaint shall be in writing and shall contain:

- (1) The name, address, telephone number, and e-mail address of the complaining party;
- (2) The dispute(s) in which the complaining party has interacted with the arbitrator;
- (3) The specific allegations on which the complaint is based;
- (4) The requested discipline;
- (5) The signature of the complaining party; and
- (6) The date on which the complaint was prepared.

b. The board shall serve on the arbitrator written notice of the complaint within 14 days of receipt of the complaint and in accordance with rule 621—2.15(20).

14.9(4) *Preliminary investigation.* Upon receipt of a complaint from an affected person or party, the board shall conduct a preliminary investigation into the allegations. In conducting the investigation, the board may require the production of evidence, including affidavits and documents. If the investigation reveals the complaint has no basis in fact or if the complaint is informally resolved with the approval of the board, the complaint shall be dismissed and the parties notified in accordance with rule 621—2.15(20).

14.9(5) *Procedures.* If the complaint is not dismissed following the preliminary investigation, the board shall schedule the complaint for hearing and notify the parties in accordance with rule 621—2.2(20). The hearing shall be held within 60 days of the completion of the preliminary investigation or the filing of a board-initiated complaint. The hearing and all subsequent proceedings and filings shall be in accordance with 621—Chapter 2.

14.9(6) *Timely resolution of complaints.* Complaints filed with the board shall be resolved within 180 days unless good cause is shown for an extension. The board will notify the parties prior to taking action to extend this time limitation upon its own motion.
[ARC 1642C, IAB 10/1/14, effective 11/5/14]

621—14.10(20) Inactive status. A roster member who continues to meet the criteria for listing on the roster shall inform the agency if the member is unavailable for selection on a temporary basis because of illness, vacation, schedule, or other reasons. That member's name will not be included on a list of arbitrators sent to parties during the period in which the member is unavailable.
[ARC 1642C, IAB 10/1/14, effective 11/5/14]

These rules are intended to implement Iowa Code sections 20.1, 20.6, 20.22 and 279.17.

[Filed ARC 1642C (Notice ARC 1570C, IAB 8/6/14), IAB 10/1/14, effective 11/5/14]

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38.1(1) Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, by-product material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

38.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of November 5, 2014.

38.1(3) The provisions of Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapter 37 and Chapters 39 to 45.

[**ARC 8982B**, IAB 8/11/10, effective 9/15/10; **ARC 1479C**, IAB 6/11/14, effective 7/16/14; **ARC 1639C**, IAB 10/1/14, effective 11/5/14]

641—38.2(136C) Definitions. As used in these rules, these terms have the definitions set forth below and are adopted by reference and included herein for 641—Chapters 39 to 45.

“Absorbed dose” means the energy imparted by ionizing radiation per unit mass of irradiated material. It is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The units of absorbed dose are the gray (Gy) and the rad.

“Absorbed dose rate” means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

“Accelerator” means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, “particle accelerator” is an equivalent term.

“Accelerator-produced material” means any material made radioactive by a particle accelerator.

“Act” means 1984 Iowa Acts, chapter 1286, relating to regulation of radiation machines and radioactive materials. (Iowa Code chapter 136C)

“Activity” means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

“Adult” means an individual 18 years of age or older.

“Agency” means the Iowa department of public health.

“Agreement state” means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954 as amended (73 Stat. 689).

“Airborne radioactive material” means any radioactive material dispersed in the air in the form of dusts, fumes, particles, mists, vapors, or gases.

“Airborne radioactivity area” means a room, enclosure, or area in which airborne radioactive material (composed wholly or partly of licensed material) exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

“Air kerma (K)” means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing

particles liberated by uncharged ionizing particles in air of mass dm . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

“Air-purifying respirator” means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

“Annually” means at least once every 365 days.

“As low as is reasonably achievable” (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

“Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

“Assigned protection factor (APF)” means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

“Atmosphere-supplying respirator” means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

“Background radiation” means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. “Background radiation” does not include sources of radiation from radioactive materials regulated by the agency.

“Barrier” (see “Protective barrier”).

“Beam axis” means a line from the source through the centers of the X-ray fields.

“Beam-limiting device” means a field defining collimator, integral to the system, which provides a means to restrict the dimensions of the X-ray field or useful beam.

“Beam monitoring system” means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

“Becquerel” (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

“Bioassay” means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, “radiobioassay” is an equivalent term.

“Bone densitometry unit” means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

“Brachytherapy” means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

“Brachytherapy source” means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

“By-product material” means:

1. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “by-product material” within this definition;

3. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity or any material that:

- Has been made radioactive by use of a particle accelerator; and
- Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

- The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat to the public health and safety or the common defense and security similar to the threat posed by a discrete source of radium-226; and

- Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

“*Cabinet radiography*” means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

“*Calendar quarter*” means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method of determining calendar quarters for purposes of these rules except at the beginning of a year.

“*Calibration*” means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

“*Carrier*” means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

“*CFR*” means Code of Federal Regulations.

“*Changeable filters*” means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

“*Collective dose*” means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

“*Committed dose equivalent*” ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

“*Committed effective dose equivalent*” ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

“*Consignment*” means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

“*Consortium*” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a federal facility or a medical facility.

“*Constraint*” or “*dose constraint*” means a value above which specified licensee actions are required.

“Controlled area” means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

“Critical group” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

“Curie” means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).

“Decay-in-storage” means the holding of radioactive material having half-lives of less than 65 days, except Cobalt-57, until it decays to background levels. Before disposal in ordinary trash, the material must have been held for a minimum of ten half-lives and its radioactivity is indistinguishable from background as indicated by a survey meter set on its most sensitive scale with no interposing shielding.

“Decommission” means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or
2. Release of the property under restricted conditions and termination of the license.

“Deep dose equivalent” (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

“Demand respirator” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

“Depleted uranium” means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

“Detector” (see “Radiation detector”).

“Diagnostic clinical procedures manual” means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

“Diagnostic imaging system” means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

“Diagnostic X-ray imaging system” means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image which are designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

“Direct supervision” means guidance and instruction by a qualified individual who is physically present and watching the performance of the radiological operation or procedure and in such proximity that contact can be maintained and immediate assistance can be given as required.

“Discrete source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

“Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

“Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

“Dose” is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, “radiation dose” is an equivalent term.

“Dose equivalent (H_T)” means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

“Dose limits” means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, “limits” is an equivalent term.

“Effective dose equivalent (H_E)” means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

“Embryo/fetus” means the developing human organism from conception until the time of birth.

“Entrance or access point” means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

“Exposure” means being exposed to ionizing radiation or to radioactive material.

“Exposure” means the quotient of dQ by dm where “ dQ ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “ dm ” are completely stopped in air. (The special unit of exposure is the roentgen (R) (see 38.2(136C) for SI equivalent coulomb per kilogram). When not underlined as above or when indicated as ‘exposure’ or (X), the term “exposure” has a more general meaning in these rules.

“Exposure rate” means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

“External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

“Extremity” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee. See 641—subrule 42.1(2) for definitions of “lower extremities” and “upper extremities” for purposes of certification standards.

“Facility” means the location, building, vehicle, or complex under one administrative control, at which radioactive material is stored or used or at which one or more radiation machines are installed, located or used.

“Filtering facepiece (dust mask)” means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, which is not equipped with elastomeric sealing surfaces and adjustable straps.

“Fit factor” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

“Fit test” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

“Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities” means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

“Generally applicable environmental radiation standards” means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

“Gray (Gy)” means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (1 Gy=100 rad).

“Half-value layer (HVL)” means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

“Hazardous waste” means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

“Healing arts” means the occupational fields of diagnosing or treating disease, providing health care and improving health by the practice of medicine, osteopathy, chiropractic, podiatry, dentistry, nursing, veterinary medicine, and supporting professions, such as physician assistants, nurse practitioners, radiologic technologists, and dental hygienists.

“Helmet” means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

“High dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate in excess of 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

“High-level radioactive waste” or *“HLW”* means (1) irradiated reactor fuel; (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and (3) solids into which such liquid wastes have been converted.

“High radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual’s receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

“Highway route controlled quantity” means a quantity within a single package which exceeds:

1. 3,000 times the A_1 value of the radionuclides as specified in 49 CFR 173.435 for special form Class 7 (radioactive) material;
2. 3,000 times the A_2 value of the radionuclides as specified in 49 CFR 173.435 for normal form Class 7 (radioactive) material; or
3. 1,000 TBq (27,000 Ci), whichever is least.

“Hood” means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

“Human use” means the internal or external administration of radiation or radioactive material to human beings.

“Individual” means any human being.

“Individual monitoring” means the assessment of:

1. Dose equivalent by the use of devices designed to be worn by an individual or by the use of survey data; or
2. Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. See the definition of DAC-hours in 641—Chapter 40.

“Individual monitoring devices” means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, “personnel dosimeter” and “dosimeter” are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescent (OSL) devices, and personal air sampling devices.

“Industrial radiography” means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

“Inspection” means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

“Instrument traceability” means, for ionizing radiation measurements, the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be from a laboratory accredited by a program which required continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

“Interlock” means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

“Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

“Ionizing radiation.” See “Radiation.”

“Irradiation” means the exposure of a living being or matter to ionizing radiation.

“Kilovolt (kV)(kilo electron volt (keV))” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum.

“Lead equivalent” means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

“Leakage radiation” means radiation emanating from the diagnostic or therapeutic source assembly except for:

1. The useful beam, and
2. Radiation produced when the exposure switch or timer is not activated.

“Lens dose equivalent (LDE)” applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

“License” means a license issued by the agency in accordance with the rules adopted by the agency.

“Licensed (or registered) material” means radioactive material received, possessed, used, transferred or disposed of under a general or specific license (or registration) issued by the agency.

“Licensed practitioner” means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, or dentistry in Iowa, or certified as a physician assistant as defined in Iowa Code section 148C.1, subsection 6, and is authorized to prescribe X-ray tests for the purpose of diagnosis or treatment.

“Licensee” means any person who is licensed by the agency in accordance with these rules and the Act.

“Licensing state” means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

“Light field” means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

“Limits.” See “Dose limits.”

“Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

“Lost or missing licensed (or registered) source of radiation” means licensed (or registered) source of radiation whose location is unknown. This definition includes licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

“Lot tolerance percent defective” means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

“Low dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate of less than or equal to 200 rads (2 gray) per hour at the point or surface where the dose is prescribed.

“mA” means milliamperere.

“Major processor” means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this rule.

“Mammography” means the radiography of the breast except as defined in 641—subrule 41.6(1).

“Mammography unit” means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the supporting structures for these components.

“Manual brachytherapy” means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

“Medical use” means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

“Medium dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

“Member of the public” means any individual except when that individual is receiving an occupational dose.

“Minor” means an individual less than 18 years of age.

“Misadministration” means the administration of:

Radiation doses received from linear accelerator therapy, deep X-ray machine therapy or superficial therapy; involving;

Administration of external beam radiation that results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin; and either:

(1) The total dose delivered differs from the prescribed dose by 20 percent or more; or

(2) The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

(1) An administration of the wrong treatment modality.

(2) An administration to the wrong patient or human research subject.

A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

“Monitoring (radiation monitoring, radiation protection monitoring)” means the measurement of radiation levels, radioactive material concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

“NARM” means any naturally occurring or accelerator-produced radioactive material. It does not include by-product, source, or special nuclear material.

“Natural radioactivity” means radioactivity of naturally occurring nuclides. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc., (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for licensing state designation purposes.

“Negative pressure respirator (tight fitting)” means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

“Nuclear Regulatory Commission (NRC)” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

“Occupational dose” means the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to radiation or to radioactive material from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

“Package” means the packaging together with its radioactive contents as presented for transport.

“Particle accelerator.” See “Accelerator.”

“Patient” means an individual or animal subjected to healing arts examination, diagnosis or treatment.

“Peak tube potential” means the maximum value of the potential difference across the X-ray tube during an exposure.

“Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

“Personnel monitoring equipment.” See “Individual monitoring devices.”

“Phantom” means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

“Pharmacist” means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

“Physician” means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy.

“Positive pressure respirator” means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

“Positron emission tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

“Powered air-purifying respirator (PAPR)” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

“Preceptor” means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

“Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented:

1. In a written directive; or
2. In accordance with the directions of the authorized user for procedures performed in 641—subrules 41.2(31) and 41.2(33).

“Prescribed dose” means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, particle accelerators and X-ray therapy systems, the total dose and dose per fraction as documented in the written directive;
3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

“Pressure demand respirator” means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

“Primary dose monitoring system” means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.

“Primary protective barrier” (see “Protective barrier”).

“Principal activities,” as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

“Protective barrier” means a barrier used to reduce radiation exposure. The types of protective barriers are as follows:

1. *“Primary protective barrier”* means the material, excluding filters, placed in the useful beam.
2. *“Secondary protective barrier”* means a barrier sufficient to attenuate the stray radiation to the required degree.

“Public dose” means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released under 641—subrule 41.2(27) or from voluntary participation in medical research programs.

“Pyrophoric material” means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C) or solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

“Qualified expert” means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

“Qualitative fit test (QLFT)” means a pass-fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

“Quality factor” (Q) means the modifying factor, listed in Tables I and II of 38.4(4), that is used to derive dose equivalent from absorbed dose.

“Quantitative fit test (QNFT)” means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

“Rad” means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

“Radiation” means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

“Radiation area” means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

“Radiation detector” means a device which, in the presence of radiation, by either direct or indirect means, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

“Radiation dose.” See “Dose.”

“Radiation machine” means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

“Radiation safety officer” means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

“Radioactive material” means any solid, liquid, or gas which emits radiation spontaneously.

“Radioactivity” means the transformation of unstable atomic nuclei by the emission of radiation.

“Radiobioassay.” See “Bioassay.”

“Radiographic imaging system” means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

“Radionuclide” means a radioactive element or a radioactive isotope.

“Registrant” means any person who is registered with the agency or is legally obligated to register with the agency pursuant to these rules and the Act.

“Registration” means registration with the agency in accordance with the rules adopted by the agency.

“Regulations of the U.S. Department of Transportation” means the regulations in 49 CFR Parts 100-189.

“Rem” means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

“Reportable medical event” means the medical event, except for an event that results from patient intervention, in which the administration of by-product material or radiation from by-product material results in:

a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

1. The total dose delivered differs from the prescribed dose by 20 percent or more;
2. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

b. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

1. An administration of the wrong radioactive drug containing by-product material;
2. An administration of a radioactive drug containing by-product material by the wrong route of administration;
3. An administration of a dose or dosage to the wrong individual or human research subject;
4. An administration of a dose or dosage delivered by the wrong mode of treatment; or
5. A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

d. An event resulting from intervention of a patient or human research subject in which administration of by-product material or radiation from by-product material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

“Research and development” means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

“Residual radioactivity” means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 641—Chapter 40 or any previous state or federal licenses, rules or regulations.

“Restricted area” means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

“Roentgen” means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (see *“Exposure”* and 38.4(4)).

“Scattered radiation” means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary

radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

“Sealed source” means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

“Secondary dose monitoring system” means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

“Secondary protective barrier” (see “Protective barrier”).

“Self-contained breathing apparatus (SCBA)” means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

“Shallow dose equivalent” (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²).

“Shutter” means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

“SI” means the abbreviation for the International System of Units.

“Sievert” means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

“Simulator (radiation therapy simulation system)” means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

“Site area emergency” means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off site.

“Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

“Source” means the focal spot of the X-ray tube.

“Source material” means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
2. Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

“Source material milling” means any activity that results in the production of by-product material as defined by definition (2) of by-product material.

“Source of radiation” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

“Source traceability” means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology or by a laboratory which participates in continuing measurement quality assurance programs with the National Institute of Standards and Technology or other equivalent national or international program.

“Special form radioactive material” means radioactive material which satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
3. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

“Special nuclear material” means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the agency declares by order to be special nuclear material after the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

“Special nuclear material in quantities not sufficient to form a critical mass” means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

“SSD” means the distance between the source and the skin entrance plane of the patient (see *“Target-to-skin distance (TSD)”*).

“Stray radiation” means the sum of leakage and scattered radiation.

“Supplied-air respirator (SAR)” or *“airline respirator”* means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

“Survey” means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

“Target-to-skin distance (TSD)” means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron virtual source scattering foil to the surface of the irradiated object or patient.

“Teletherapy” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“Termination of irradiation” means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“Test” means the process of verifying compliance with an applicable regulation.

“These rules” means 641—Chapters 38 to 45.

“Tight-fitting facepiece” means a respirator inlet covering that forms a complete seal with the face.

“Total effective dose equivalent” (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

“Total organ dose equivalent” (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 641—40.86(1) “f.”

“Traceable to a national standard.” See *“Instrument traceability”* or *“Source traceability.”*

“Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in the written directive.

“Tube” means an X-ray tube unless otherwise specified. See *“X-ray tube.”*

“Tube housing assembly” means the tube housing with tube installed. It includes high-voltage or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.

“Type A quantity” means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 , for normal form radioactive material as defined in 10 CFR 71.4.

“Type B quantity” means a quantity of radioactive material greater than a Type A quantity as defined in 10 CFR 71.4.

“Unrefined and unprocessed ore” means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

“Unrestricted area” means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these rules, “uncontrolled area” is an equivalent term.

“U.S. Department of Energy” means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

“User seal check (fit check)” means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

“Very high radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual’s receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.

“Waste” means those low-level radioactive wastes containing source, special nuclear, or by-product material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or by-product material as defined in paragraphs “2,” “3” and “4” of the definition of “by-product material” set forth in this chapter.

“Waste handling licensees” means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

“Wedge filter” means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

“Week” means seven consecutive days starting on Sunday.

“Whole body” means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

“Worker” means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

“Working level” (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-lived radon daughters are—for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

“Working level month” (WLM) means an exposure to 1 working level for 170 hours—2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

“Written directive” means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or by an individual qualified by training and experience to conduct particle accelerator therapy or radiation for X-ray therapy, as specified in 641—subrule 41.2(87).

“X-radiation” means penetrating electromagnetic radiation with energy greater than 0.1 kV produced by bombarding a metallic target with fast electrons in a high vacuum.

“X-ray tube” means any electron tube which is designed to be used primarily for the production of X-rays.

“Year” means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to

determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—38.3(136C) Exemptions from the regulatory requirements.

38.3(1) General provision. The agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in 641—Chapters 38 to 46 as it determines are authorized by law and will not result in undue hazard to public health and safety or property. Application for exemptions or exceptions should be made in accordance with 641—Chapter 178.

38.3(2) Persons using by-product material under certain Department of Energy and Nuclear Regulatory Commission contracts.

a. Except to the extent that NRC facilities or activities of the types subject to licensing pursuant to the Energy Reorganization Act of 1974 are involved, any prime contractor of the NRC is exempt from the license requirements of these rules and from the regulations of these rules to the extent that such contractor, under the contractor's prime contract with the NRC, manufactures, produces, transfers, receives, acquires, owns, possesses, or uses by-product material for:

(1) The performance of work for a department at the United States government-owned or government-controlled site, including the transportation of by-product material to or from such site and the performance of contract services during temporary interruptions of such transportation;

(2) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(3) The use or operation of nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.

b. In addition to the foregoing exemptions and subject to the requirement for licensing of NRC facilities and activities pursuant to the requirements of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the NRC is exempt from the requirements for a license set forth in the Act and from the regulations in these rules to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, or uses by-product material under the contractor's or subcontractor's prime contract or subcontract when the NRC determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

c. Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from these rules to the extent that they transport or store radioactive material in the regular course of carriage for another or of storage incident thereto.

641—38.4(136C) General regulatory requirements.

38.4(1) Records.

a. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

b. Electronic records.

(1) A record or signature shall not be denied legal effect or enforceability solely because it is in electronic form.

(2) A contract shall not be denied legal effect or enforceability solely because an electronic record was used in its formation.

(3) If a rule requires a record to be in writing, an electronic record shall satisfy the rule.

(4) If a rule requires a signature, an electronic signature shall satisfy the rule.

38.4(2) Inspections.

a. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

38.4(3) Tests. Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

- a.* Sources of radiation;
- b.* Facilities wherein sources of radiation are used or stored;
- c.* Radiation detection and monitoring instruments; and
- d.* Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

38.4(4) Units of exposure and dose.

a. As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent (see footnote "1")
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

1. Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

b. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 38.4(4) "*a.*," 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² Sv ⁻¹)
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8

Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² Sv ⁻¹)
1E-1	7.5	170E+6	170E+8
5E-1	11	39E+6	39E+8
1	11	27E+6	27E+8
2.5	9	29E+6	29E+8
5	8	23E+6	23E+8
7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

^aValue of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

^bMonoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

38.4(5) Units of activity. Rescinded IAB 4/8/98, effective 7/1/98.

38.4(6) Additional requirements. The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

641—38.5(136C) Administrative actions. Rescinded IAB 4/3/02, effective 5/8/02.

641—38.6(136C) Prohibited uses. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe-fitting fluoroscopic device shall not be used. Radiation from radiation-emitting machines or radioactive materials shall not be used on humans for nonmedical purposes.

641—38.7(136C) Communications.

38.7(1) All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, Des Moines, Iowa 50319.

38.7(2) Drafts of proposed regulations released to the department from the federal government which constitute essential information needed by the department to ensure compliance with federal regulations are not available for public examination. Therefore, pursuant to Iowa Code section 22.9, the department waives the provision of Iowa Code section 22.2 as it applies to these proposed draft regulations.

641—38.8(136C) Fees.

38.8(1) Radiation machines.

a. Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a nonrefundable fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually in the form of a check or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

ANNUAL FEE SCHEDULE

Type of X-ray machine	Fee per tube	Maximum fee
1. Medical	\$51	\$1500
2. Osteopathy	\$51	\$1500
3. Chiropractic	\$51	\$1500
4. Dentistry	\$39	\$1000
5. Podiatry	\$39	\$1000
6. Veterinary Medicine	\$25	—
7. (Industrial/Nonmedical Use)	\$50	—
8. Food Sterilization	\$1000	—
9. Accelerators and Electronic Brachytherapy Units	\$100	—
10. Electron Microscope	\$20	—
11. Bone Densitometry	\$25	—

Fees for radiation machines not listed in the above schedule shall not be less than \$50 per unit/tube.

b. Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

- \$900 for the first unit and, if the facility has additional units at the address of the first unit, a fee of \$325 for each additional unit; or
- \$900 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or
- Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or
- \$450 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; or
- \$900 for each stereotactic breast biopsy unit.

(2) Mammography interpretation fees of \$100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.

(3) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of \$400 for the first unit and \$100 for each additional unit.

(4) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of \$250 for the first unit and \$75 for each additional unit.

c. Each person who is engaged in the business of installing or offering to furnish radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or service in the state shall apply for registration of such service with the agency prior to furnishing or offering to furnish any such service. Application shall be on a form provided by the department and include an annual nonrefundable fee of \$100.

d. Each person engaged in providing health physics services in mammography in Iowa, who meets the requirements of 641—paragraph 41.6(3)“c” and is deemed qualified by this agency, must submit a \$40 annual listing fee to this agency.

e. All mammography facilities providing services in Iowa must submit a \$50 annual authorization certification fee.

f. All Iowa-accredited facilities providing mammography services in Iowa must submit a \$200 accreditation fee for initial accreditation and each reaccreditation.

38.8(2) Radioactive material fee schedule. Fees associated with the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31 and 10 CFR 171.16. The following fee schedule shall apply.

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(3.L.)	01100	AAB	Academic Type A Broad	\$5,000	1	\$10,500
(8.A.)	03710	CD	Civil Defense	\$1,000	5	\$1,000
(3.E.)	03510	I1	Irradiators, Self-Shielding <10,000 Curies	\$2,000	5	\$650
(3.O.)	03320	IR1	Industrial Radiography – Temporary Job Sites	\$4,500	1	\$4,300
(3.P.)	03120	FG	Measuring Systems – Fixed Gauge	\$1,300	5	\$650
(3.P.)	03121	PG	Measuring Systems – Portable Gauge	\$1,300	5	\$650
(3.P.)	02410	IVL	<i>In-Vitro</i> Testing Laboratory	\$1,300	5	\$650
(7.C.)	02230	HDR	High Dose Rate Afterloader	\$2,300	1	\$3,400
(7.C.)	02120	M1	Medical – Diagnostic & Therapy	\$2,300	3	\$1,500
(7.C.)	02121	M2	Medical – Diagnostic Only	\$2,300	4	\$1,200
(7.C.)	02240	MET	Medical – Diagnostic, Therapeutic, Emerging Technologies	\$2,300	2	\$2,000
(3.S.)	03210	PET	Accelerator-Produced RAM	\$3,000	1	\$4,300
(3.C.)	02500	NP	Nuclear Pharmacy	\$3,000	1	\$3,500
(7.C.)	02231	NV1	Nuclear Medical Van	\$2,300	2	\$1,800
(7.C.)	22160	PMM	Pacemaker – By-Product and/or SNM	\$2,300	T	Note 5
(3.M.)	03620	RD2	Research & Development – Other	\$2,500	3	\$1,350
(2.C.)	11300	SM1	Source Material, Other, >150 Kilograms	\$6,000	3	\$2,250
(1.D.)	22120	SNM2	SNM Plutonium – Neutron Source	\$1,500	5	\$500
(3.P.)	03221	CAL	Calibration and W/L Tests	\$1,300	5	\$650
(3.P.)	03122	XRF	X-Ray Fluorescent Analyzer	\$1,300	7	\$650
(3.P.)	02400	VMT	Veterinary Medicine – Therapy	\$1,300	3	\$650
(3.B.)	03214	MD	Manufacturing/Distribution	\$3,500	3	\$1,800

Notes:

1. Reciprocity fee is \$1,800 annually (180 days).
2. Inspection priorities are based on NRC inspection manual chapter 2800. Priority “T” is a telephonic contact and is not considered an inspection.
3. License amendment fee for all categories is \$400.
4. Annual fees are due no later than September 1 of each year. A 10% late charge will be assessed per month for late payments. Licensees with more than two authorized locations of use will be charged an additional 10% of the annual fee per location.
5. Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses with the agency.
6. General license registration fee is \$250 annually on registration anniversary.

38.8(3) *Industrial radiography testing and certification.*

a. A nonrefundable fee of \$175 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

b. A fee of \$25 shall be submitted in order to replace lost identification cards issued to industrial radiographers by the agency pursuant to 641—subrule 45.1(10).

c. A nonrefundable fee of \$75 shall be submitted with each application, not associated with an agency-administered industrial radiography examination, for a trainee or trainer card issued to a radiographer's assistant or an industrial radiographer.

38.8(4) *Owner-assessed expenses.* In cases in which the agency determines that the cost of regulating or inspecting registered radiation machine facilities or radioactive materials licensees significantly exceeds the fees charged to the facility, it may assess an additional fee to the owner or user of the source(s) of radiation to cover the actual expenses incurred by the agency.

38.8(5) *Environmental surveillance fee.* A fee may be levied against any licensee, registrant, corporation, company, business, or individual for environmental surveillance activities which are necessary to assess the radiological impact of activities conducted by the licensee, registrant, corporation, company, business, or individual. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required.

38.8(6) *Certification fees.* Rescinded IAB 2/6/13, effective 3/13/13.

38.8(7) *Returned check and late fees.* Persons who fail to pay required fees to the agency are subject to the following penalties:

a. \$25 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. \$25 for each month for failure to pay any fee administered by this agency starting 30 days after the due date of the original notice. This fee is added to the unpaid fee.

38.8(8) *Reciprocity.* Fees paid for reciprocal recognition of out-of-state persons wishing to utilize radiation machines or radioactive materials in Iowa shall allow the out-of-state person to operate for a total of 180 days during the 365-day reciprocity period starting the date the fee is received by the agency.

a. Radiation machines. Any out-of-state person who wishes to bring an X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of \$100 for each source of radiation.

b. Radioactive materials. Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)). If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in the radioactive materials fee schedule available through the agency for each 365-day reciprocity period. In addition, if the agency performs an inspection of the out-of-state person's activities while in Iowa, the appropriate inspection fee as specified in the radioactive materials fee schedule will be assessed.

c. Industrial radiographers wishing to operate in Iowa under an identification card from a jurisdiction recognized by Iowa that charges Iowa card holders a fee will be assessed and must pay a \$100 fee prior to conducting industrial radiography in Iowa.

38.8(9) *Radon certification.* Rescinded IAB 4/3/02, effective 5/8/02.

38.8(10) *Radon mitigation credentialing.* Rescinded IAB 4/3/02, effective 5/8/02.

38.8(11) *Radioactive material transport fee schedule.*

a. All shippers shall pay the following fee(s) unless the department obtains sufficient funding from another source, which may include but is not limited to a federal agency or a contract with a shipper.

(1) \$1800 per highway cask for each truck shipment of spent nuclear fuel, high-level radioactive waste, transuranic waste, or highway route controlled quantity of radioactive materials or any material shipped in accordance with rule 641—37.77(136C) traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of \$20 per mile for every mile over 250 miles traveled.

(2) \$1300 for the first cask and \$125 for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste, transuranic waste, or any material shipped in accordance with rule 641—37.77(136C) traversing the state or any portion thereof.

(3) \$175 for each shipment by truck or by rail paid by the shipper for low-level radioactive waste shipped in or across Iowa. The department may accept an annual shipment fee as negotiated with a shipper or accept payment per shipment. This fee applies to waste shipped to a site authorized by a government agency to receive low-level radioactive waste or shipped to a storage site to be held for future disposal.

b. All fees must be paid by the shipper prior to shipment. Shippers must request an application for a permit to ship radioactive material from the Iowa Department of Transportation, Office of Motor Carrier Services. Assistance may be obtained by calling the Bureau of Radiological Health at (515)281-3478. Other methods of fee payment may be considered by the department on a case-by-case basis upon request of the shipper. A request for an alternative method of payment must be made to the department prior to shipment.

c. All fees received pursuant to this subrule shall be used for purposes related to transporting radioactive material, including enforcement and planning, developing, and maintaining a capability for emergency response.

38.8(12) Fee waiver. Any fee may be waived in exchange for services (low-level waste disposal, radiation detection instrument calibration, instrument repair, sample analysis, etc.) provided to the agency. The waiver may only occur as a result of a 28E agreement between the parties.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—38.9(136C) Administrative enforcement actions.

38.9(1) Scope.

a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term “regulated entity” as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation. “Authorization” means license, registration, certificate, permit, or any other document issued or received by the agency that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4, to impose serious misdemeanor penalties pursuant to Iowa Code section 136B.5 or to impose simple misdemeanor penalties pursuant to Iowa Code section 136D.8.

38.9(2) Notice of violation.

a. In response to an alleged violation of any provision of the Iowa Code, these rules, the conditions of an authorization issued by the agency or any order issued by the agency, the agency may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to 38.9(3) or demand for information pursuant to 38.9(5) is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:

- (1) Corrective steps which have been taken by the regulated entity and the results achieved;
- (2) Corrective action which will be taken to prevent recurrence; and
- (3) The date when full compliance will be achieved.

b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the agency may issue an order or

a demand for information as to why the authorization should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

c. Violations are categorized according to five levels of severity, which are:

(1) Severity Levels I and II: Violations are of very significant regulatory concern involving actual or high potential impact on the public health and safety.

(2) Severity Level III: Violations are cause for significant concern.

(3) Severity Level IV: Violations are less serious but are of more than minor concern and that, if left uncorrected, could lead to a more serious health and safety concern.

(4) Severity Level V: Violations are of minor safety or environmental concern.

d. A group of violations may be evaluated in the aggregate and assigned a single higher severity level if the violations have the same underlying cause or if the violations contributed to or were unavoidable consequences of the underlying problem.

e. The severity level of a violation may be increased if the violation can be considered a repetitive violation. The term “repetitive violation” or “similar violation” means a violation that reasonably could have been prevented by a regulated entity’s corrective action for a previous violation normally occurring within the past two years of the inspection at issue or the period within the last two inspections, whichever is longer.

f. The severity level of a violation may be increased if the violation involves casual disregard of requirements, deception, or other indications of willfulness. The term “willfulness” is that characteristic of violations ranging from deliberate intent to violate or falsify to intentional disregard for regulatory requirements.

38.9(3) Orders.

a. The agency may institute a proceeding to modify, suspend, or revoke an authorization or to take other action as may be proper by serving on the regulated entity an order which will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient grounds for the proposed action;

(2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order;

(3) Inform the regulated entity of its right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the regulated entity has consented in writing to the order;

(4) Specify the issues for hearing; and

(5) State the effective date of the order; if the agency finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

b. A regulated entity who receives an order may respond to an order under this subrule by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order and may set forth the matters of fact and law on which the regulated entity relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph “d” of this subrule, the answer may demand a hearing.

c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the agency, and shall be effective as provided in the order.

38.9(4) Settlement and compromise. At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a

regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty.

38.9(5) Demand for information.

a. The agency may issue to a regulated entity a demand for information for the purpose of determining whether an order under 38.9(3) should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the regulated entity must file a written answer to the demand for information under oath or affirmation within 20 days of its date, or such time as may be specified in the demand for information.

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity's answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer filed pursuant to 38.9(5) "a"(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to 38.9(3) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in 38.9(3) "d."

38.9(6) Civil penalties.

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6) "b," an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6) "a."

d. If the person charged with violation files an answer to the notice of violation, the agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The agency may compromise any civil penalty, subject to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6) “*c*” or “*f*,” or the expiration of the time for requesting a hearing described in 38.9(6) “*d*,” the agency may refer the matter to the attorney general for collection.

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

38.9(7) *Requests for action under this rule.*

a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke an authorization as may be proper. Such a request shall be addressed to the Chief, Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The bureau chief will discuss the matter with staff to determine appropriate action in accordance with 38.9(7) “*b*.”

b. Within a reasonable time after a request pursuant to 38.9(7) “*a*” has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.

c. (1) The bureau chief’s decisions under this rule will be filed and within 25 days after the date of the bureau chief’s decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the bureau chief has abused discretion. This review power does not limit in any way either the agency’s supervisory power over delegated staff actions or the agency’s power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

(2) No petition or other request for agency review of a bureau chief’s decision under this rule will be entertained by the agency.

38.9(8) *Impounding.* The agency may impound or order the impounding of radioactive material in the possession of a person who fails to observe the provisions of Iowa Code chapter 136C, or any rules, license or registration conditions, or orders issued by this agency.

a. If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give to either the owner or the possessor of the source of radiation written notice of the intention to impound the source of radiation.

(1) Either the owner or the possessor shall have 20 days from the date of personal service of certified mailing to request a hearing, except in the case where the regulated entity has consented in writing to the impoundment.

(2) If a hearing is requested, the agency will issue an order designating the time and place of hearing.

b. At the agency’s direction, the impounded sources of radiation may be disposed of by:

(1) Returning the source of radiation to a properly licensed or registered owner that did not cause the emergency;

(2) Returning the source of radiation to a licensee or registrant after the emergency is over and after settlement of any compliance action; or

(3) Selling, destroying, or disposing of the source of radiation in another manner within the agency’s discretion.

641—38.10(136C) *Deliberate misconduct.*

38.10(1) Any licensee, registrant, applicant for a license or certificate of registration, employee of a licensee, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or registrant or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, registrant, contractor, or

subcontractor any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities in this rule, may not:

a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the agency; or

b. Deliberately submit to the agency, a licensee, registrant, applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the agency.

38.10(2) A person who violates paragraph 38.10(1) "a" or "b" may be subject to enforcement action in accordance with the procedures in 641—38.9(136C).

38.10(3) For the purposes of paragraph 38.10(1) "a," deliberate misconduct by a person means an intentional act or omission that the person knows:

a. Would cause a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the agency; or

b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

These rules are intended to implement Iowa Code chapter 136C.

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[Filed ARC 1639C (Notice ARC 1470C, IAB 5/28/14), IAB 10/1/14, effective 11/5/14]

◊ Two or more ARCs

¹ Effective date of 38.8(11) delayed 70 days from May 9, 2001, by the Administrative Rules Review Committee at its meeting held May 4, 2001.

At its meeting held July 10, 2001, the Committee delayed the effective date until adjournment of the 2002 Session of the General Assembly.

CHAPTER 39

REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

641—39.1(136C) Purpose and scope.

39.1(1) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

39.1(2) No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 16, 2014.

39.1(4) In addition to the requirements of this chapter, all registrants are subject to the requirements of 641—Chapters 38 and 40. Furthermore, registrants engaged in healing arts are subject to the requirements of 641—Chapters 41 and 42; registrants engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45.

39.1(5) In areas under exclusive federal jurisdiction, nothing in these rules applies to the extent that persons are subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) or other federal agencies.

[ARC 7983B, IAB 7/29/09, effective 9/2/09; ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—39.2(136C) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 38 may also apply to this chapter.

641—39.3(136C) Requirements for registration of X-ray and other electronic machines that produce radiation.**39.3(1) Exemptions.**

a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 µSv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

b. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

c. Domestic television receivers are exempt from the requirements of this chapter.

39.3(2) Application for registration of radiation machine facilities. Each person having a radiation machine facility shall:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a storage area located in Iowa where records of equipment maintenance and quality assurance, personnel monitoring, and personnel certification must be kept for review during an inspection. The records may be stored on a van, if appropriate. An Iowa mailing address is not required. Application for registration shall be completed on forms furnished by the agency and shall include the appropriate fee from 641—38.8(136C).

b. Designate on the application form an individual to be responsible for radiation protection.

c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 39.3(3)“d” to the registrant’s radiation machine facility until such person provides evidence that the person has been registered with the agency as a provider of services in accordance with 39.3(3).

39.3(3) Application for registration of servicing and services.

a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services

in this state shall apply for registration of such services with the agency prior to furnishing or offering to furnish any such services.

b. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions and include the fee required in 641—paragraph 38.8(1) “c.”

c. Each person applying for registration under this chapter shall specify:

- (1) That the person has read and understands the requirements of these rules;
- (2) The services for which the person is applying for registration;
- (3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;
- (4) The type of measurement instrument to be used, frequency of calibration, and source of calibration; and
- (5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

d. For the purpose of 39.3(3), services may include but shall not be limited to:

- (1) Installation and servicing of radiation machines and associated radiation machine components;
- (2) Calibration of radiation machines or radiation measurement instruments or devices;
- (3) Radiation protection or health physics consultations or surveys; and
- (4) Processor or processor servicing, or both.
- (5) Calibration and compliance surveys of external beam radiation therapy units.

e. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.

f. A registration may be revoked for violating or causing a facility to violate any of the rules in 641—Chapters 38 through 45.

g. Radiation therapy physicists providing services for therapeutic radiation machines must provide proof that the training requirements of 641—subrule 41.3(6) have been met.

39.3(4) Issuance of notice of registration.

a. Upon a determination that an applicant meets the requirements of this chapter, the agency shall issue a notice of registration.

b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant’s receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

39.3(5) Expiration of notice of registration. Except as provided by 39.3(6) “b,” each notice of registration shall expire within 12 months of issuance or at the end of the specified day in the month and year stated therein.

39.3(6) Renewal of notice of registration.

a. Application for renewal of registration shall be filed in accordance with 39.3(2) or 39.3(3).

b. In any case in which a registrant has properly filed an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration shall not expire until the application status has been finally determined by the agency.

39.3(7) Report of changes. The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration or the notice of registration no longer accurate.

39.3(8) Approval not implied. No person, in any advertisement, shall refer to the fact that the person or the person’s facility is registered with the agency pursuant to the provisions of 39.3(2) or 39.3(3), and no person shall state or imply that any activity under such registration has been approved by the agency.

39.3(9) Assembler and transfer obligation.

a. Any person who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the agency in writing within 15 days of:

- (1) The name and address of persons who have received these machines;
- (2) The manufacturer, model, and serial number of each radiation machine transferred; and

(3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, shall meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X-ray systems which contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

39.3(10) Reciprocity—out-of-state radiation machines.

a. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least three working days before such machine is to be used in the state. The notice shall include:

- (1) The type of radiation machine;
- (2) The nature, duration, and scope of use;
- (3) The exact location(s) where the radiation machine is to be used; and
- (4) States in which this machine is registered.

b. If, for a specific case, the three-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

c. The person referred to in 39.3(10)“a” shall:

- (1) Comply with all applicable rules of the agency;
- (2) Supply the agency with such other information as the agency may reasonably request; and
- (3) Not operate within the state on a temporary basis in excess of 180 calendar days in a 365-day reciprocity period. The 365-day reciprocity period starts on the day the agency receives the appropriate fee, as specified in 641—subrule 38.8(8), and ends exactly 365 days later. It is the registrant's responsibility to ensure the 180-day limit is not exceeded during the 365-day reciprocity period and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the 365-day reciprocity period.

39.3(11) Exemption. Rescinded IAB 4/8/98, effective 7/1/98.

641—39.4(136C) Requirements for licensing of radioactive materials.

39.4(1) Additional requirements.

a. In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40.

b. An Iowa radioactive materials license requires that the person have a permanent storage area in Iowa where records are maintained pertaining to licensed activities, equipment maintenance and quality assurance, personnel monitoring, and personnel certification and where material can be stored. The records may be stored on a van, if appropriate. The storage area must be accessible during inspections. An Iowa mailing address is not required.

39.4(2) Source material.

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. Any person is exempt from the requirements for a license set forth in this chapter and from the rules in this chapter and 641—Chapter 40 to the extent that such person receives, possesses, uses, or transfers:

- (1) Any quantities of thorium contained in:
 1. Incandescent gas mantles,
 2. Vacuum tubes,
 3. Welding rods,
 4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
 5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,
 6. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or
 7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.
- (2) Source material contained in the following products:
 1. Glazed ceramic tableware manufactured before November 5, 2014, provided that the glaze contains not more than 20 percent by weight source material,
 2. Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before November 5, 2014, 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,
 3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or
 4. Piezoelectric ceramic containing not more than 2 percent by weight source material.
- (3) Photographic film, negatives, and prints containing uranium or thorium.
- (4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.
- (5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
 1. Reserved.
 2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM,"
 3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED," and
 4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.
- (6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:
 1. The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM," and
 2. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).
- (7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before November 5, 2014, 30 percent by weight of thorium; and that this exemption does not authorize either:
 1. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror, or

2. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Rescinded IAB 10/1/14, effective 11/5/14.

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thorium (thorium dioxide), and

2. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

d. The exemptions in 39.4(2) do not authorize the manufacture of any of the products described.

e. The requirements specified in 39.4(2) “c”(5) “2” and “3” need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, “CAUTION—RADIOACTIVE MATERIAL—URANIUM,” as previously required by the rules.

f. No person may initially transfer for sale or distribution a product containing source material to persons exempt under these rules, or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

(1) Persons initially transferring for sale or distributing source material in products covered by the exemptions in these rules before November 5, 2014, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(2) Persons authorized to manufacture, process, or produce these materials or products containing source material by the agency, an agreement state, or the Nuclear Regulatory Commission, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of 641—Chapter 40 and 39.4(25) “a” and “b.”

39.4(3) *Radioactive material other than source material.*

a. Exempt concentrations.

(1) Except as provided in 39.4(3) “a”(2), any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this chapter.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 39.4(3) “a”(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any agreement state, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

(3) An exemption is granted to persons who receive, possess, use, process, transfer, distribute, and dispose of materials containing or contaminated at concentrations less than 20 picocuries per gram of radium.

(4) This rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(5) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license and from these rules to the extent that the manufacturer, processor, or producer transfers radioactive material contained in a product or material in concentrations not in excess of the requirements in Appendix A of this chapter and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

b. Exempt quantities.

(1) Except as provided in 39.4(3) “b”(3), (4), and (5), any person is exempt from the requirements for a license and from these rules to the extent that such person receives, possesses, uses, transfers, owns,

or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

(2) Any person who possesses radioactive material received or acquired under a general license is exempt from the requirements for a license set forth in this chapter to the extent that such person possesses, uses, transfers or owns such radioactive material.

(3) This paragraph (39.4(3) “b”) does not authorize for purposes of commercial distribution the production, packaging, repackaging or transfer of radioactive material or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 39.4(3) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR 32, which license states that the radioactive material may be transferred by the licensee to persons exempt under 39.4(3) “b” or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of this chapter, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

c. Exempt items.

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

1. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

- 25 millicuries (925 MBq) of tritium per timepiece;
- 5 millicuries (185 MBq) of tritium per hand;
- 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);
- 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;
- 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;
- 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);
- One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

2. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

- For wrist watches, 0.1 millirad (1 μ Gy) per hour at 10 centimeters from any surface.
- For pocket watches, 0.1 millirad (1 μ Gy) per hour at 1 centimeter from any surface.
- For any other timepiece, 0.2 millirad (2 μ Gy) per hour at 10 centimeters from any surface.

3. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

4. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

5. Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:

- 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;
- 1 microcurie (37 kBq) of cobalt-60;
- 5 microcuries (185 kBq) of nickel-63;
- 30 microcuries (1.11 MBq) of krypton-85;
- 5 microcuries (185 kBq) of cesium-137; and
- 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad (10 μ Gy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. For purposes of 39.4(3)“c”(1)“5,” the term “electron tubes” includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

6. Ionizing radiation measuring instruments, for purposes of internal calibration or standardization, containing one or more sources of radioactive material, provided that:

- Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;
- Each device contains no more than ten exempt quantities. For purposes of this requirement, a device’s source(s) may contain either one type of or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or
- For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 39.4(3)“c”(1)“6.”

7. Ionization chamber smoke detectors containing not more than 1 microcurie (μ Ci) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

Any person who desires to apply by-product material to, or to incorporate by-product material into, the products exempted in subparagraph 39.4(3)“c”(1), or who desires to initially transfer for sale or distribution such products containing by-product material, should apply for a specific license with the Nuclear Regulatory Commission pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to subparagraph 39.4(3)“c”(1).

(2) Self-luminous products containing radioactive material.

1. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under these rules. Any person who desires to manufacture, process, produce or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use according to this paragraph shall apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210. The exemption in 39.4(3)“c”(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. Radium-226. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of these rules.

(3) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from the requirements contained in 641—Chapters 38, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 20, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to 39.4(3)“c”(3)“1,” shall apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210.

(4) 1. Static elimination devices which contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.

2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3. Such devices authorized before November 5, 2014, for use under the general license that was provided in 39.4(22)“a” and equivalent regulations of an agreement state or the Nuclear Regulatory Commission and manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the agency.

(5) Radioactive drug: capsules containing carbon-14 urea for “in vivo” diagnostic use for humans.

1. Except as provided in paragraphs “b” and “c” of this subrule, any person is exempt from the requirements for a license set forth in this chapter and in 641—41.2(136C) provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq 1µCi carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for “in vivo” diagnostic use for humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 641—41.2(136C).

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 39.4(20) of this rule.

4. Nothing in this subrule relieves persons from complying with applicable FDA or other federal or state requirements governing receipt, administration, and use of drugs.

(6) Certain industrial devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under these rules. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing by-product material for use under these rules should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

39.4(4) to 39.4(19) Reserved.

39.4(20) *Types of licenses.* There are two types of licenses for radioactive materials: general and specific.

a. General licenses provided in this chapter are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of a certificate or registration application with the agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these rules and any limitations of the general license.

b. Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

c. All licensees and registrants must submit the appropriate fee in 641—subrule 38.8(2).

39.4(21) *General licenses—source material.*

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and federal, state and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of November 5, 2014, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the agency takes final action on a pending application submitted on or before November 5, 2015, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the agency takes final action on a pending application submitted on or before November 5, 2015, for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of 39.4(21) “a”(1); or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

b. Any person who receives, possesses, uses, or transfers source material in accordance with the general license issued in 39.4(21) “a”:

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

1. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this chapter to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

2. In accordance with 641—40.70(136C).
- (3) Is subject to the provisions in 641—38.4(136C), 641—38.9(136C), 39.4(21), 39.4(32) “a” through “d” and “f,” 39.4(41), 39.4(51), 39.4(52), 641—40.95(136C), 641—40.96(136C), and 641—40.97(136C).
- (4) Reserved.
- (5) Shall not export such source material except in accordance with 10 CFR Part 110.
- c. Any person who receives, possesses, uses, or transfers source material in accordance with 39.4(21) “a” shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 641—40.29(136C).
- d. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.
- e. Depleted uranium in industrial products and devices.
 - (1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 39.4(21) “e”(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
 - (2) The general license in 39.4(21) “e”(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 39.4(29) “m” or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.
 - (3) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 39.4(21) “e”(1) shall file Agency Form “Registration Certificate—Use of Depleted Uranium Under General License” with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on the Agency Form “Registration Certificate—Use of Depleted Uranium Under a General License” the following information and such other information as may be required by that form:
 - Name and address of the general licensee;
 - A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 39.4(21) “e”(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
 - Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 39.4(21) “e”(3) “1.”
 2. The general licensee possessing or using depleted uranium under the general license established by 39.4(21) “e”(1) shall report in writing to the agency any changes in information furnished by the general licensee in Agency Form “Registration Certificate—Use of Depleted Uranium Under General License.” The report shall be submitted within 30 days after the effective date of such change.
 - (4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 39.4(21) “e”(1):
 1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
 2. Shall not abandon such depleted uranium;
 3. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 39.4(41). In the case where the transferee receives the depleted uranium pursuant to

the general license established by 39.4(21) "e"(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of Agency Form "Registration Certificate—Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21) "e"(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of the Agency Form "Registration Certificate—Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 641—Chapters 38, 39, 40, 41 and 45;

4. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

5. Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 39.4(21) "e"(1) is exempt from the requirements of 641—Chapter 40 with respect to the depleted uranium covered by that general license.

f. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 39.4(21) "a" is exempt from the provisions of 641—Chapter 40 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 641—40.29(136C) and 641—40.70(136C) to the extent necessary to meet the provisions of 39.4(21) "b"(2) and 39.4(21) "c." However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

g. No person may initially transfer or distribute source material to persons generally licensed under 39.4(21) "a"(1) and (2), or equivalent regulations of the Nuclear Regulatory Commission or an agreement state, unless authorized by a specific license issued in accordance with 39.4(39) or equivalent provisions of the Nuclear Regulatory Commission or an agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by 39.4(21) "a" before November 5, 2014, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the agency takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before November 5, 2015.

39.4(22) General licenses—radioactive material other than source material. This subrule establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. (Note: Different general licenses are issued in this subrule, each of which has its own specific conditions and requirements.)

a. Rescinded IAB 10/1/14, effective 11/5/14.

b. and c. Reserved.

d. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of 39.4(22) "d"(2), (3), and (4), radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in 39.4(22) "d"(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license by this agency issued under 39.4(29) "d"; or an equivalent specific license issued by the NRC or an agreement state or a licensing state; or an equivalent specific license issued by a state with provisions comparable to 39.4(29) "d," which authorizes distribution of the devices.

The devices must have been received from one of the specific licensees described in 39.4(22) “d”(2) or through a transfer made under 39.4(22) “d”(3).

(3) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in 39.4(22) “d”(1):

1. Shall ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. Shall ensure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; However,

- Devices containing only krypton need not be tested for leakage of radioactive material; and
- Devices containing only tritium or not more than 100 microcuries of other beta- or gamma-emitting material or both or 10 microcuries of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

3. Shall ensure that the test required by 39.4(22) “d”(3) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment are performed:

- In accordance with the instructions provided by the labels; or
- By a person holding a specific license pursuant to 641—39.4(136C), the NRC, an agreement state or a licensing state to perform such activities;

4. Shall maintain records showing compliance with the requirements of 39.4(22) “d”(3). The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

- Each record of a test for leakage of radioactive material required by 39.4(22) “d”(3) must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
- Each record of a test of the on-off mechanism and indicator required by 39.4(22) “d”(3) must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of;
- Each record that is required by 39.4(22) “d”(3) must be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

5. Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by this agency, the NRC, an agreement state or licensing state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by this agency. A report containing a brief description of the event and the remedial action taken, and in the case of detection of 0.005 microcurie (185 Bq) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the agency within 30 days. Under these circumstances, the criteria set out in 641—40.29(136C) may be applicable, as determined by the agency on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

7. Shall not export the device containing radioactive material except in accordance with 10 CFR Part 110;

8. Shall transfer or dispose of the device containing radioactive material only by export as provided by 39.4(22) “d”(3)“7,” by transfer to another general licensee as authorized in 39.4(22) “d”(3)“9,” to a person authorized to receive the device by a specific license issued by the agency, the NRC, an agreement

state or a licensing state whose specific license authorizes the person to receive the device or which authorizes waste collection, or as otherwise approved under 39.4(22) “d”(3):

- Shall furnish a report to this agency within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device by manufacturer’s (or initial transferor’s) name, model number, and serial number; the name, address and license number of the person receiving the device (license number not applicable if device is exported); and the date of the transfer;

- Shall obtain written agency approval before transferring the device to any other specific licensee not specifically identified in 39.4(22) “d”; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

- Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

- Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 39.4(22) “d”(3)“1”) so that the device is labeled in compliance with 641—40.63(136C) of these rules; however the manufacturer, model number, and serial number must be retained;

- Obtains manufacturer’s or initial transferor’s information concerning maintenance that would be applicable under the specific license (such as leak-testing procedures); and

- Reports the transfer under 39.4(22) “d”(3)“8” of this chapter.

9. Shall transfer the device to another general licensee only if:

- The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of these rules and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to this agency the manufacturer’s (or initial transferor’s) name; the model number and the serial number of the device transferred; the transferee’s name and mailing address for the location of use; and the name, title, and telephone number of the responsible individual identified by the transferee in accordance with 39.4(22) “d”(3)“12” to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or

- The device is held in storage, by an intermediate person, in the original shipping container at its intended location of use prior to initial use by a general licensee;

10. Shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—Chapter 40;

11. Shall respond to written requests from this agency to provide information relating to the general license within 30 calendar days of the date of the request, or other item specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the agency and providing written justification as to why it cannot comply;

12. Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

13. Shall register as follows:

- Shall register devices as approved in the Sealed Source Device Registry. Each address for a location of use, as described in 39.4(22) “d”(3)“13,” represents a separate general licensee and requires a separate registration and fee;

- If in possession of devices meeting the criteria of 39.4(22) “d”(3)“13,” shall register these devices annually with the agency and shall pay the fee required in 641—paragraph 38.8(2)“c.” Registration must be done by verifying, correcting, and adding to the information provided in a request for registration received from the agency. The registration information must be submitted 30 days from the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of 39.4(22) “d”(3)“13” is subject to the bankruptcy notification requirement of 39.4(32) “e”;

- In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the agency:

- Name and mailing address of the general licensee;
- Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);
- Name, title, and telephone number of the responsible person designated as a representative of the general licensee;
- Address or location at which the device(s) is both used and stored. For portable devices, the address of the primary place of storage;
- Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and check of label information.
- Certification by the responsible representative of the general licensee that the licensee is aware of the requirements of the general license.

- Persons generally licensed by this agency under 39.4(22) “d”(3) “13” or an agreement state are not subject to registration requirements of 39.4(22) “d”(3) “13” if the devices are used in areas subject to this agency’s jurisdiction for a period of less than 180 days in any calendar year. The agency will not request registration information from such licensees;

14. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the agency within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device’s primary place of storage; and

15. May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 39.4(22) “d” need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in 39.4(22) “d”(1) does not authorize the manufacture or import of devices containing radioactive material.

(5) A general license to install devices generally licensed in 39.4(22) “d.” Any person who holds a specific license issued by an agreement state authorizing the holder to manufacture, install, or service a device described in 39.4(22) “d” within such agreement state is hereby granted a general license to install and service such device in any non-agreement state and a general license to install and service such device in offshore waters, as defined in 641—45.1(136C), provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with the applicable provision of the specific license issued to such person by the agreement state, and

2. Such person ensures that any labels required to be affixed to the device under regulations of the agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

e. Luminous safety devices for aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

1. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 39.4(22) “e”(1) are exempt from the requirements of 641—Chapter 40 except that they shall comply with the provisions of 641—40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

f. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

g. Calibration and reference sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 39.4(22) “g”(4) and (5), americium-241 in the form of calibration or reference sources:

1. Any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material; and

2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the person to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 39.4(22) “g”(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 39.4(22) “g”(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(4) The general licenses in 39.4(22) “g”(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 39.4(22) “g”(1), (2), and (3) are subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

1. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium-226 in such sources;

2. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

- The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM-241).

(PLUTONIUM) (showing only the name of the appropriate material) DO NOT TOUCH
RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

OR

- The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS RADIUM-226.
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

3. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to receive the source;

4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

h. Reserved.

i. General license for use of radioactive material for certain in vitro clinical or laboratory testing. The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 39.4(22) “i”(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

1. Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.
2. Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.
3. Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
4. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.
5. Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.
6. Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.
7. Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
8. Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 39.4(22) “i”(1) until the person has filed an Agency Form “Certificate—In Vitro Testing with Radioactive Material Under General License” with the agency and received from the agency a validated copy of the form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish the following information on the form and such other information as may be required by the form:

1. Name and address of the physician, veterinarian, clinical laboratory or hospital;
2. The location of use; and
3. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 39.4(22) “i”(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 39.4(22) “i”(1) shall comply with the following:

1. The general licensee shall not possess at any one time, pursuant to the general license in 39.4(22) "i"(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 200 microcuries (7.4 MBq).

2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

3. The general licensee shall use the radioactive material only for the uses authorized by 39.4(22) "i"(1).

4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

5. The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in 39.4(22) "i"(1) "8" as required by 641—subrule 40.70(1).

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 39.4(22) "i"(1):

1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 39.4(29) "h" or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under 39.4(22) "i" or its equivalent, and

2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

- This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 39.4(22) "i"(1) shall report in writing to the agency any changes in the information furnished in the "Certificate—In Vitro Testing with Radioactive Material Under General License," Agency Form V. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 39.4(22) "i"(1) is exempt from the requirements of 641—Chapter 40 with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in 39.4(22) "i"(1) "8" shall comply with the provisions of 641—subrule 40.70(1) and rules 40.95(136C) and 40.96(136C).

j. Ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 39.4(22) “j”(1):

1. Shall, upon occurrence of visually observable damage such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 641—subrule 40.70(1);

2. Shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

3. Are exempt from the requirements of 641—Chapter 40 except that such persons shall comply with the provisions of 641—subrule 40.70(1), and rules 40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

k. Certain items and self-luminous products containing radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with 39.4(22) “k”(2), (3), and (4), radium-226 contained in the following products manufactured prior to November 30, 2007.

1. Antiquities originally intended for use by the general public. For the purposes of this subrule, “antiquities” means products originally intended for use by the general public and distributed in the late nineteenth and early twentieth centuries including, but not limited to, radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2. Intact and non-intact timepieces containing greater than 1 microcurie (0.037 megabecquerel), and timepiece hands and dials no longer installed in timepieces.

3. Luminous items installed in air, marine, or land vehicles.

4. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

5. Small radium sources containing no more than 1 microcurie (0.037 megabecquerel) of radium-226. For the purposes of this subrule, “small radium sources” means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the agency.

(2) Persons who acquire, receive, possess, use, or transfer by-product material under the general license issued in 39.4(22) “k”(1) shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—Chapter 40, to the extent that the receipt, possession, use, or transfer of by-product material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under 39.4(24).

(3) Any person who acquires, receives, possesses, uses, or transfers by-product material in accordance with the general license in 39.4(22) “k”(1) shall:

1. Notify the agency if there is any indication of possible damage to the product which could result in a loss of the radioactive material. A report containing a brief description of the event and the remedial action taken must be furnished to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa, within 30 calendar days.

2. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 641—40.77(136C) or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the agency.

3. Not export products containing radium-226 except in accordance with 10 CFR Part 110.

4. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under 39.4(24), or equivalent NRC or agreement state requirements, or as otherwise approved by the agency.

5. Respond in writing to a written request from the agency to provide information relating to the general license within 30 calendar days of the request, or other time specified in the request.

(4) The general license in 39.4(22)“k”(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

39.4(23) Reserved.

39.4(24) *Filing application for specific licenses.*

a. Applications for specific licenses shall be filed on a form prescribed by the agency and include the fee required in 641—subrule 38.8(2).

b. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

f. (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix G of this chapter, must contain either:

1. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2. An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under 39.4(24)“f”(1)“1” of this subrule:

1. The radioactive material is physically separated so that only a portion could be involved in an accident;

2. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

3. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix G due to the chemical or physical form of the material;

4. The solubility of the radioactive material would reduce the dose received;

5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix G;

6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix G; or

7. Other factors appropriated for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under 39.4(24)“f”(1)“2” must include the following information:

1. Facility description. A brief description of the licensee's facility and area near the site.

2. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

3. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

4. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

5. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

6. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.

8. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

9. Information to be communicated. A brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.

10. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

11. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub.L.No. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

g. (1) Except as provided in 39.4(24) “g”(2), (3), and (4), an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material as registered with a state under provisions comparable to 10 CFR 32.210; or

2. Contain the information identified in 10 CFR 32.210(c).

(2) For sources or devices manufactured prior to November 5, 2014, that are not registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all the categories of information specified in 10 CFR 32.210(c), the application must include:

1. All available information identified in 10 CFR 32.210(c) concerning the source and, if applicable, the device; and

2. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a current leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

h. An application from a medical facility or an educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in the facility’s or educational institution’s consortium authorized for medical use under 641—41.2(136C) or equivalent NRC or agreement state requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this chapter or equivalent NRC or agreement state requirements for a PET production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 39.4(29) “j”(1)“2.”

(3) Identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 39.4(29) “j”(2)“2.”

(4) Information identified in 39.4(29) “j”(1)“3” on the PET drugs to be noncommercially transferred to members of the facility’s consortium.

39.4(25) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 641—Chapters 38, 39, 40, 41 and 45 in such a manner as to minimize danger to public health and safety or property;

b. The applicant’s proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public; and

d. The applicant satisfies any applicable special requirements in 39.4(26), 39.4(27), 39.4(28), 641—41.2(136C), or 641—Chapter 45.

e. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement

of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

39.4(26) *Financial assurance and record keeping for decommissioning.*

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding $1.0E^5$ times the applicable quantities set forth in Appendix F of 641—Chapter 40 shall submit a decommissioning funding plan as described in 39.4(26) "e." The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F.

b. (1) Each holder of or applicant for a specific license authorizing possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in 39.4(26) "d" (or when a combination of isotopes is involved if R , as defined in 39.4(26) "a," divided by 10^{12} is greater than 1) shall submit a decommissioning funding plan as described in 39.4(26) "e."

(2) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 39.4(26) "d" shall either:

1. Submit a decommissioning funding plan as described in 39.4(26) "e"; or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 39.4(26) "d" using one of the methods described in 39.4(26) "f." For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26) "f" must be submitted before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26) "f."

c. (1) Each holder of a specific license issued on or after July 1, 1993, which is of a type described in 39.4(26) "a" or "b," shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subrule.

(2) Each holder of a specific license issued before July 1, 1993, and of a type described in 39.4(26) "a," shall submit, on or before January 1, 2007, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this subrule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(36) "b," shall submit, on or before July 1, 1993, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subrule.

(4) Any licensee who submitted an application before July 1, 2003, for renewal of license shall provide financial assurance for decommissioning in accordance with 39.4(26) "a" and "b."

(5) Waste collectors and waste processors must provide financial assurance in an amount based on a decommissioning funding plan as described in 39.4(26) "e." The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license,

and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 641—Chapters 39 and 40.

(6) If, in surveys made under 641—subrule 40.36(1), residual radioactivity in the facility and the environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 641—40.29(136C) criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

d. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26) "a," divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1.) 1,125,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26) "a," divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1.) 225,000

Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of Appendix F or 641—Chapter 40 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 39.4(26) "a," divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.) 113,000

Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan

e. (1) Each decommissioning funding plan must be submitted for review and approval and must contain:

1. A detailed cost estimate for decommissioning, in an amount reflecting:
 - The cost of an independent contractor to perform all decommissioning activities;
 - The cost of meeting the 641—40.29(136C) criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 641—40.30(136C), the cost estimate may be based on meeting the 641—40.30(136C) criteria;
 - The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
 - An adequate contingency factor;
2. Identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);
3. A description of the method of assuring funds for decommissioning from 39.4(26) "f," including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and
5. A signed original of the financial instrument obtained to satisfy the requirements of 39.4(26) "f" (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be

done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;
2. Waste inventory increasing above the amount previously estimated;
3. Waste disposal costs increasing above the amount previously estimated;
4. Facility modifications;
5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. Onsite disposal; and
8. Use of a settling pond.

f. The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this chapter. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subrule. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix H of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix I of this chapter. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix J of this chapter. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of paragraph 39.4(26) "f" or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

1. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

2. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

3. The surety method or insurance must remain in effect until the agency has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 39.4(26) "f"(2).

(4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in 39.4(26) "d," and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity assumes custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

g. Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is released for unrestricted use. Before licensed activities are transferred or assigned to another licensee, the licensee shall transfer all records described in this subrule to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. All areas designated as restricted areas as defined under 641—38.2(136C);
2. All areas outside of restricted areas that require documentation under 641—39.4(26) "g"(1);
3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 641—40.88(136C); and

4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal in accordance with 641—40.71(136C).

39.4(27) *Special requirements for issuance of certain specific licenses for radioactive material.*

a. to d. Reserved.

e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 39.4(25), a specific license for use of sealed sources in industrial radiography will be issued if the application contains:

- (1) A schedule or description of the program for training radiographic personnel which specifies:
 1. Initial training,
 2. Periodic training,

3. On-the-job training, and
4. Methods to be used by the licensee to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, licensing requirements, and the operating and emergency procedures of the applicant;
 - (2) Written operating and emergency procedures, including all items listed in Appendix D of 641—Chapter 45;
 - (3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow license provisions, rules of the agency, and the applicant's operating and emergency procedures;
 - (4) A list of permanent radiographic installations and descriptions of permanent storage and use locations. Radioactive material shall not be stored at a permanent storage location or used at a permanent use location unless such storage or use location is specifically authorized by the license. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any of the following applies to the location:
 1. Non-wireless telephone service is established by the licensee;
 2. Industrial radiographic services are advertised for or from the location;
 3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location;
 - (5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program;
 - (6) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including applicable items in 641—subrule 45.1(8) and 641—Chapter 45, Appendix A); and
 - (7) If a license application includes underwater radiography, a description of:
 1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
 2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
 3. Methods for gas-tight encapsulation of equipment;
 - (8) If a license application includes offshore platform or lay-barge radiography, a description of:
 1. Transport procedures for radioactive material to be used in industrial radiographic operations;
 2. Storage facilities for radioactive material; and
 3. Methods for restricting access to radiation areas.

39.4(28) *Special requirements for specific licenses of broad scope.* This subrule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

a. The different types of broad scope licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A “Type C specific license of broad scope” is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

b. An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25);

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

2. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

3. The establishment of appropriate administrative procedures to ensure:

- Control of procurement and use of radioactive material;

- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

- Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 39.4(28) “b”(3)“3” prior to use of the radioactive material.

c. An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

2. The establishment of appropriate administrative procedures to ensure:

- Control of procurement and use of radioactive material;

- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

- Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 39.4(28) “c”(2)“2” prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

1. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

2. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to ensure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 39.4(28) shall not:

1. Conduct tracer studies in the environment involving direct release of radioactive material;
2. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;
3. Conduct activities for which a specific license issued by the agency under 39.4(27), 39.4(29) or 641—41.2(136C) is required; or
4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 39.4(28) "d."

39.4(29) *Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.*

a. Rescinded IAB 7/29/09, effective 9/2/09.

b. Rescinded IAB 3/30/05, effective 5/4/05.

c. Rescinded IAB 7/29/09, effective 9/2/09.

d. Licensing the manufacture and distribution of devices to persons generally licensed under 39.4(22) "d."

(1) An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 39.4(22) "d" or equivalent regulations of the NRC, an agreement state, or a licensing state will be approved if:

1. The applicant satisfies the general requirements of 39.4(25);
2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - The device can be safely operated by persons not having training in radiological protection,
 - Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the annual limits specified in 641—40.15(136C); and
 - Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming

organs; gonads; or lens

of eye 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized

areas of skin averaged

over areas no larger

than 1 square centimeter 200 rems (2 Sv)

Other organs. 50 rems (500 mSv)

3. Each device bears a durable, legible, clearly visible label or labels approved by the agency, NRC, or agreement state or licensing state, which contains in a clearly identified and separate statement:

- Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide this information;
- The requirement, or lack of requirement, for leak testing, or for testing any “on-off” mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
- The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, (devices licensed prior to January 19, 1975, may bear labels authorized by the rules in effect on January 1, 1975)(the model, serial number, and name of the manufacturer or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device) are subject to a general license or the equivalent and the chapter of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

Name of manufacturer or initial transferor

4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words “Caution—Radioactive Material,” the radiation symbol described in 641—subrule 40.60(1), and the name of the manufacturer or initial distributor;

5. Each device meeting the criteria of 39.4(22) “d”(3)“13” bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, “Caution—Radioactive Material,” and, if practicable, the radiation symbol described in 641—subrule 40.60(1); and

6. The device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the “on-off” mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the “on-off” mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:

1. Primary containment or source capsule;
2. Protection of primary containment;
3. Method of sealing containment;
4. Containment construction materials;
5. Form of contained radioactive material;
6. Maximum temperature withstood during prototype tests;
7. Maximum pressure withstood during prototype tests;
8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and
10. Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 39.4(22)“d,” or under equivalent regulations of the NRC, an agreement state, or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the “on-off” mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in 641—40.15(136C).

(4) Information to be provided before transfer.

1. If a device containing radioactive material is to be transferred for use under the general license contained in 39.4(22)“d,” each person that is licensed under 39.4(22)“d” shall provide the information specified to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- A copy of the general license contained in 39.4(22), or if 39.4(22)“d”(3)“2,” “3,” or “4” or 39.4(22)“d”(3)“13” does not apply to the particular device, those paragraphs may be omitted;
- A copy of 39.4(20), 39.4(52), 641—40.95(136C), and 641—40.96(136C);
- A list of the services that can only be performed by a specific licensee;
- Information on acceptable disposal options including estimated costs of disposal; and
- An indication that it is the policy of the NRC and this agency to issue high civil penalties for improper disposal.

2. If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an agreement state, each person that is licensed under 39.4(29)“d” shall provide the information specified in this paragraph to each person to whom a device is to be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- A copy of the NRC or agreement state’s rules equivalent to 39.4(29)“d.” If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the agreement state’s regulations, it shall be accompanied by a note explaining that use of the device is regulated by the agreement state; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

- A list of the services that can only be performed by a specific licensee;
- Information on acceptable disposal options including estimated costs of disposal; and
- The name or title, address, and telephone number of the contact at the agreement state regulatory agency from which additional information may be obtained.

3. An alternative approach to informing customers may be proposed by the licensee for approval by the agency.

4. Each device that is transferred after February 19, 2002, must meet the labeling requirements in 39.4(29)“d.”

5. If a notification of bankruptcy has been made or the license is to be terminated, each person licensed under 39.4(29)“d” shall provide, upon request, to the NRC and to any appropriate agreement state, records of final disposition.

(5) Transfer reports and records. Each person licensed under 39.4(29)“d” to initially transfer devices to generally licensed persons shall comply with the requirements of this subparagraph.

1. The person shall report all transfers of devices to persons for use under the general license in 39.4(29)“d” and all receipts of devices from persons licensed under 39.4(29)“d” to the NRC, this agency, or another agreement state. The report must be submitted on a quarterly basis in a clear and

legible report containing all of the data required in this subrule. The required information for transfers to general licensees includes:

- The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;
- The name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

- The date of transfer;
- The type, model number, and serial number of the device transferred; and
- The quantity and type of radioactive material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address; the type, model number, and serial number of the device received; the date of receipt; and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update the required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

7. If no transfers have been made to or from persons generally licensed under 39.4(29) “d” during the reporting period, the report must so indicate.

(6) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 39.4(29) “d.” Records required in 39.4(29) “d” must be maintained for three years following the date of the recorded event.

e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 39.4(22) “e,” will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25); and
- (2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 CFR Part 32, or their equivalent.

f. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under 39.4(22) “g” will be approved if:

- (1) The applicant satisfies the general requirements of 39.4(25); and
- (2) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 CFR Part 32, or their equivalent.

g. Reserved.

h. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 39.4(22) “i” will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25).
- (2) The radioactive material is to be prepared for distribution in prepackaged units of:
 1. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.
 2. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
 3. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

4. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

5. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

6. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

7. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

8. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

2. Displaying the radiation caution symbol described in 641—subrule 40.60(1) and the words, “CAUTION—RADIOACTIVE MATERIAL,” and “Not for Internal or External Use in Humans or Animals.”

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

1. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or an agreement state.

Name of manufacturer

2. Rescinded IAB 3/30/05, effective 5/4/05.

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 641—subrule 40.70(1).

i. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 to persons generally licensed under 39.4(22) “j” will be approved if the applicant satisfies the general requirements of 39.4(25) and the requirements of Sections 32.61 and 32.62 of 10 CFR Part 32, or their equivalent.

j. Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing by-product material for medical use under 641—41.2(136C).

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing by-product material for use by persons authorized pursuant to 641—41.2(136C) will be approved if:

1. The applicant satisfies the general requirements specified in subrule 39.4(25);

2. The applicant submits evidence that the applicant is at least one of the following:

- Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

- Registered or licensed with a state agency as a drug manufacturer;

- Licensed by the Iowa board of pharmacy as a nuclear pharmacy;

- Operating as a nuclear pharmacy within a federal medical institution; or

- A positron emission tomography (PET) drug production facility registered or licensed with a state agency;

3. The applicant submits information on the radionuclide: the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

4. The applicant satisfies the following labeling requirements:

- A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

- A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee as described by 39.4(29)“j”(1)“2”:

1. May prepare radioactive drugs for medical use, as defined in 641—38.2(136C), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 39.4(29)“j”(2)“2” and 39.4(29)“j”(2)“3” or an individual under the supervision of an authorized nuclear pharmacist as specified in 641—paragraph 41.2(11)“c.”

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

- This individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2),

- This individual meets the requirements specified in 641—subrules 41.2(77) and 41.2(78) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

- This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)“j”(2)“3.”

3. May designate a pharmacist (as defined in 641—subrule 41.2(2)) as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

4. Shall permit the actions authorized in 39.4(29)“j”(2)“1” and “2” that are permitted in spite of more restrictive language in license conditions.

5. Shall provide to the agency a copy of each individual’s:

- Certification by a specialty board whose certification process has been recognized by the NRC or an agreement state as specified in 641—paragraph 41.2(78)“a” with the written attestation signed by a preceptor as required by 641—paragraph 41.2(78)“c”; or

- NRC or agreement state license; or

- NRC master materials licensee permit; or

- Permit issued by a licensee or NRC master materials permittee of broad scope or authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

- Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

- State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(29)“j”(2)“2,” first and third bulleted paragraphs, the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by

direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

1. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

2. Check each instrument for constancy and proper operation at the beginning of each day of use.

- (4) Nothing in this subrule relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

k. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have their reagent kits approved by the agency for use by persons licensed pursuant to 641—subrule 41.2(33) may submit the pertinent information specified in 39.4(29)“*k.*” An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this chapter for the uses listed in 641—subrule 41.2(33) will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25);

- (2) The applicant submits evidence that:

1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a “Notice of Claimed Investigational Exemption for a New Drug” (IND) that has been accepted by the FDA, or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

- (3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

- (4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

- (5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the agency pursuant to 641—subrule 41.2(33) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The labels, leaflets, or brochures required by 39.4(29)“*k.*” are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

l. Manufacture and distribution of sources or devices containing radioactive material for medical use.

- (1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration, transmission, or reference source or for the uses listed in 641—subrules 41.2(41), 41.2(43), 41.2(49), and 41.2(88) will be approved if:

1. The applicant satisfies the general requirements in 39.4(25);

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

- The radioactive material contained, its chemical and physical form, and amount,
- Details of design and construction of the source or device,
- Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
- For devices containing radioactive material, the radiation profile of a prototype device,
- Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests,
- Procedures and standards for calibrating sources and devices,
- Legend and methods for labeling sources and devices as to their radioactive content, and
- Instructions for handling and storing the source or device from the radiation safety standpoint.

These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the NRC, agreement state, or this agency has approved distribution of the source or device to persons licensed to use by-product material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, and to persons who hold an equivalent license issued by the NRC or an agreement state; and

4. The source or device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(3) In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

1. Primary containment or source capsule,
2. Protection of primary containment,
3. Method of sealing containment,
4. Containment construction materials,
5. Form of contained radioactive material,
6. Maximum temperature withstood during prototype tests,
7. Maximum pressure withstood during prototype tests,
8. Maximum quantity of contained radioactive material,
9. Radiotoxicity of contained radioactive material, and
10. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

m. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 39.4(21)“d” or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 39.4(25);
2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 641—40.15(136C) of these rules; and

3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide

reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under 39.4(29)“m” only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license under 39.4(29)“m” if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 39.4(29)“m”(1) shall:

1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

2. Label or mark each unit to:

- Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

- State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

3. Ensure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: “Depleted Uranium”

4. Furnish a copy of the general license contained in 39.4(21)“d” and a copy of the agency form used to register the device to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license contained in 39.4(21)“d,” or furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission’s or agreement state’s regulation equivalent to 39.4(21)“d” and a copy of the U.S. Nuclear Regulatory Commission’s or agreement state’s certificate, or alternatively, furnish a copy of the general license contained in 39.4(21)“d” and a copy of the agency form used to register to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 39.4(21)“d”;

5. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 39.4(21)“d.” Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 39.4(21)“d” during the reporting period, the report shall so indicate;

6. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40; and shall report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 39.4(29)“m” for use under a general license in that state’s regulations equivalent to 39.4(21)“d.” Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission. If no transfers have been made to general licensees within a particular agreement state during the reporting

period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and

7. Keep records showing the name, address, and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 39.4(21) “d” or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 641—Chapters 39 and 40.

n. Rescinded IAB 7/29/09, effective 9/2/09.

o. Acceptance sampling procedures under certain specific licenses. A random sample shall be taken from each inspection lot of devices licensed under 39.4(29) for which testing is required and meet the requirements pursuant to 10 CFR 32.110.

39.4(30) Reserved.

39.4(31) *Issuance of specific licenses.*

a. Upon a determination that an application meets the requirements of the Iowa Code and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee’s receipt, possession, use, and transfer of radioactive material subject to this chapter as it deems appropriate or necessary in order to:

- (1) Minimize danger to public health and safety or property;
- (2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
- (3) Prevent loss or theft of material subject to this chapter.

c. Specific license for industrial radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

- (1) The applicant satisfies the general requirements specified in 39.4(25).
- (2) The applicant submits an adequate program for training radiographers and radiographers’ assistants that meets the requirements of 641—subrule 45.1(10).
- (3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.
- (4) The applicant submits written operating and emergency procedures as described in 641—subrule 45.2(4).

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer’s assistant at intervals not to exceed six months as described in 641—subrule 45.1(11).

(6) The applicant submits a description of the applicant’s overall organizational structure as it applies to the radiation responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (641—paragraph 45.1(10) “d”) and potential designees responsible for ensuring that the licensee’s radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform “in-house” calibrations of survey instruments, the applicant must describe the methods to be used and the relevant experience of the person(s) who will perform

the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 641—subrule 45.1(5).

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by 641—Chapters 38, 39, 40, and 45 will be located.

d. Specific licenses for well logging. The agency will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:

(1) The applicant shall satisfy the general requirements specified in 39.4(25) and all other requirements in 641—Chapter 39, as appropriate, and any special requirements contained in 39.4(31) “*d.*”

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the agency a description of this program which specifies the following:

1. Initial training;

2. On-the-job training;

3. Annual safety reviews provided by the licensee;

4. The means the applicant will use to demonstrate the logging supervisor’s knowledge and understanding of and ability to comply with the agency’s regulations and licensing requirements and the applicant’s operating and emergency procedures; and

5. The means the applicant will use to demonstrate the logging assistant’s knowledge and understanding of and ability to comply with the applicant’s operating and emergency procedures.

(3) The applicant shall submit to the agency written operating and emergency procedures as described in 641—subrule 45.6(16) or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the agency its program for annual inspections of the job performance of each logging supervisor to ensure that the agency’s regulations and license requirements and the applicant’s operating and emergency procedures are followed. Inspection records must be retained for three years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as the organizational structure applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the agency. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

39.4(32) *Specific terms and conditions of licenses.*

a. Each license issued pursuant to this chapter shall be subject to all the provisions of the Iowa Code, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Iowa Code, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing. An application for transfer of license must include:

(1) The identity and technical and financial qualifications of the proposed transferee; and

(2) The financial assurance for decommissioning information required by 39.4(26).

c. Each person licensed by the agency pursuant to this chapter shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

d. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

e. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 641—subrule 41.2(34). The licensee shall record the results of each test and retain each record for three years after the record is made.

f. Each general licensee that is required to register by 39.4(21) or 39.4(22) and each specific licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (1) The licensee;
- (2) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the licensee or licensee as property of the estate; or
- (3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

The notification specified in 39.4(32) “*f*” shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

g. (1) Authorization under 39.4(29) “*h*” to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in the licensee’s consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(2) Each licensee authorized under 39.4(29) “*h*” to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the licensee’s consortium shall:

1. Satisfy the labeling requirements in 39.4(29) “*j*”(1)“4” for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of the licensee’s consortium.

2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of the licensee’s consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 39.4(29) “*j*”(3).

(3) A licensee that is a pharmacy authorized under 39.4(24) “*h*” to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy’s consortium shall require that any individual who prepares PET radioactive drugs shall be:

1. An authorized nuclear pharmacist who meets the requirements in 39.4(29) “*j*”(2)“2,” or
2. An individual under the supervision of an authorized nuclear pharmacist as specified in 641—subrule 41.2(11).

(4) A pharmacy authorized under 39.4(29) “*j*” to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy’s consortium that allows an individual to work as an authorized nuclear pharmacist shall meet the requirements in 39.4(29) “*j*”(2)“5.”

39.4(33) *Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.*

a. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 39.4(33) not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

b. Each specific license revoked by the agency expires at the end of the day on the date of the agency’s final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by agency order.

c. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of by-product material until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

- (1) Limit actions involving by-product material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with state of Iowa requirements.

d. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with the state of Iowa requirements, or submit within 12 months of notification a decommissioning plan, if required by 39.4(33)“j” and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to 39.4(33)“a” or “b”;

(2) The licensee has decided to permanently cease principal activities, as defined in 641—38.2(136C) at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with state of Iowa requirements;

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area suitable for release in accordance with State of Iowa requirements.

e. Coincident with the notification required by 39.4(33)“d,” the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to subrule 39.4(26) in conjunction with a license issuance or renewal or as required by this subrule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph 39.4(33)“g.”

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective on July 9, 1997.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

f. The agency may grant a request to extend the time periods established in 39.4(33)“d” if the agency determines that this request is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 39.4(33)“d.” The schedule for decommissioning set forth in 39.4(33)“d” of this subrule may not commence until the agency has made a determination on the request.

g. A decommissioning plan must be submitted if required by license conditions or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase the potential health and safety impacts to workers or to the public.

(1) Procedures having potential health and safety impacts include, but are not limited to:

1. Procedures that would involve techniques not applied routinely during cleanup or maintenance operations;

2. Workers that would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

3. Procedures that could result in significantly greater airborne concentrations of radioactive material than are present during operation;

4. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 39.4(33)“d” of this subrule if the agency determines that the alternate schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in 39.4(33)“g” with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

1. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
2. A description of planned decommissioning activities;
3. A description of the methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
4. A description of the planned final radiation survey; and
5. An updated detailed cost estimate for decommissioning, and a plan for ensuring the availability of adequate funds for completion of decommissioning.
6. A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.
7. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include justification for the delay based on the criteria in paragraph "i" of this subrule.

(5) The proposed decommissioning plan will be approved by the agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

h. Except as provided in 39.4(33) "i," licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. When the decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

i. The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

- (1) It is technically feasible to complete decommissioning within the allotted 24-month period;
- (2) Sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;
- (3) A significant volume reduction exposure to workers can be achieved by allowing short-lived radionuclides to decay;
- (4) A significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
- (5) Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than a deferred cleanup, and other factors beyond the controls of the licensee.

j. As the final step in decommissioning, the licensee shall:

- (1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed IDPH Form 588-2793 or equivalent information; and
- (2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C). The licensee shall, as appropriate:

1. Report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report the level of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters (removable and fixed) for surfaces, microcuries (megabecquerels) per liter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

2. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the agency determines that:

- (1) By-product material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) A radiation survey has been performed which demonstrates that the premises are suitable for release or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C).

(4) Records required by 39.4(52) “e” and 39.4(52) “g” have been received.

l. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2) “d.”

m. If licensed activities are transferred or assigned in accordance with 39.4(32) “b,” each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2) “d.”

n. Prior to license termination, each licensee shall forward the records required by 39.4(26) “g” to the agency.

39.4(34) *Renewal of licenses.*

a. Applications for renewal of specific licenses shall be filed in accordance with 39.4(24) and include the fees required in 641—subrule 38.8(2).

b. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

39.4(35) *Amendment of licenses at request of licensee.* Applications for amendment of a license shall be filed in accordance with 39.4(24), include the fees required in 641—subrule 38.8(2), and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

39.4(36) *Agency action on applications to renew or amend.* In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 39.4(25), 39.4(27), 39.4(28), and 39.4(29) and in 641—Chapters 38, 40, 41, 42, 43, 44 and 45, as applicable.

39.4(37) *Persons possessing a license for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these rules.* Any person who, on the effective date of these rules, possesses a general or specific license issued by the U.S. Nuclear Regulatory Commission for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass, shall be deemed to possess a like license issued under this chapter and the Iowa Code, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

39.4(38) *Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of these rules.* Any person who, on the effective date of these rules, possesses NARM for which a specific license is required by the Iowa Code or this chapter shall be deemed to possess such a license issued under the Iowa Code and this chapter. Such license shall expire 90 days after the effective date of these rules; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

39.4(39) *Requirements for license to initially transfer source material for use under a general license.* An application for a specific license to initially transfer source material for use under 39.4(21), or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, will be approved if:

- a. The applicant satisfies the general requirements specified in 39.4(25); and
- b. The applicant submits adequate information on, and the agency approves the methods to be used for, quality control, labeling, and providing safety instructions to recipients.

39.4(40) *Conditions of licenses to initially transfer source material for use under general license: quality control, labeling, safety instructions, and records and reports.*

- a. Each person licensed under 39.4(39) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words “radioactive material.”

- b. Each person licensed under 39.4(39) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

- c. Each person licensed under 39.4(39) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under 39.4(21) or equivalent provisions in agreement state or Nuclear Regulatory Commission regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

- (1) A copy of 39.4(21) and 39.4(41) or relevant equivalent regulations of the agreement state or Nuclear Regulatory Commission.

- (2) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

- d. Each person licensed under 39.4(39) shall report transfers as follows:

- (1) File a report with the Iowa Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. The report shall include the following information:

1. The name, address, and license number of the person who transferred the source material;
 2. For each general licensee under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

- (2) File a report with each responsible agreement state agency or the Nuclear Regulatory Commission that identifies all persons, operating under provisions equivalent to 39.4(21), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state or Nuclear Regulatory Commission jurisdiction:

1. The name, address, and license number of the person who transferred the source material; and
 2. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state or Nuclear Regulatory Commission jurisdiction.

- (3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions during the current period, a report shall be submitted to the agency indicating so. If no transfers have been made to general licensees in a particular agreement state or Nuclear Regulatory Commission jurisdiction during the reporting period, this information shall be reported to the responsible agreement state agency or Nuclear Regulatory Commission upon request.

- e. Each person licensed under 39.4(39) shall maintain all information that supports the reports required by these rules concerning each transfer to a general licensee for a period of one year after the

event is included in a report to the agency, the Nuclear Regulatory Commission or to an agreement state agency.

39.4(41) *Transfer of material.*

a. No licensee shall transfer radioactive material except as authorized pursuant to 39.4(41).

b. Except as otherwise provided in the license and subject to the provisions of 39.4(41) “*c*” and “*d*,” any licensee may transfer radioactive material:

(1) To the agency (a licensee may transfer material to the agency only after receiving prior approval from the agency);

(2) To the U.S. Department of Energy;

(3) To any person exempt from these rules to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state, or a licensing state; or

(5) As otherwise authorized by the agency in writing.

c. Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee’s license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by 39.4(41) “*c*” is acceptable:

(1) The transferor may possess and read a current copy of the transferee’s specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in 39.4(41) “*d*”(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of 641—39.5(136C).

39.4(42) to 39.4(50) Reserved.

39.4(51) *Modification and revocation of licenses.*

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Iowa Code, or by reason of rules, regulations, and orders issued by the agency.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Iowa Code, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or

for violation of, or failure to observe any of the terms and conditions of the Iowa Code, or of the license, or of any rule, regulation, or order of the agency.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

39.4(52) Records.

a. Each person who receives by-product material pursuant to a license shall keep records showing the receipt, transfer, and disposal of the by-product material as follows:

(1) The licensee shall retain each record of receipt of by-product material as long as the material is possessed and for three years following transfer or disposal of material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of these rules dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of by-product material until the agency terminates each license that authorizes disposal of the material.

b. The licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition; the record must be retained until the agency terminates each license that authorizes the activity that is subject to the record-keeping requirements.

c. Records which must be maintained may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

d. If there is a conflict between the agency's rules or other written agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in these rules for such records shall apply unless the agency has granted a specific exemption from the record retention requirements specified in agency rules.

e. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Records of disposal of licensed material made under 641—40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)“d.”

f. If licensed activities are transferred or assigned, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)“d.”

g. Prior to license termination, each licensee shall forward the records required by subrule 39.4(26) to the agency.

39.4(53) to 39.4(89) Reserved.

39.4(90) Reciprocal recognition of licenses.

a. Licenses of by-product, source, and special nuclear material in quantities not sufficient to form a critical mass.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such

licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license.

(2) The licensing document referenced in 39.4(90) "a"(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three working days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90) "a."

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90) "a" except by transfer to a person specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material.

(7) Notwithstanding the provisions of 39.4(90) "a"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22) "d"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22) "d" or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10) "h."

b. Licenses of naturally occurring or accelerator-produced radioactive material.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the

licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.

(2) The licensing document referenced in 39.4(90) “a”(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90) “b.”

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90) “b” except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3) “a.”

(7) Notwithstanding the provisions of 39.4(90) “b”(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22) “d”(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that “Removal of this label is prohibited”; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22) “d” or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any

product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10) "h."

39.4(91) to 39.4(104) Reserved.

[**ARC 7983B**, IAB 7/29/09, effective 9/2/09; **ARC 8982B**, IAB 8/11/10, effective 9/15/10; **ARC 1639C**, IAB 10/1/14, effective 11/5/14]

641—39.5(136C) Transportation of radioactive material. All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the applicable provisions contained in 10 CFR Part 71 and 49 CFR Parts 170 through 189. The regulations in 10 CFR Part 71 apply to any licensee authorized by specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage, or transports that material on public highways. No provision of 10 CFR Part 71 authorizes possession of licensed material.

CHAPTER 39—APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152(9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}

Element (atomic number)	Radionuclide	Column I	Column II
		Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}

Element (atomic number)	Radionuclide	Column I	Column II
		Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

NOTE 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

NOTE 2: For purposes of 39.4(3) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1."

EXAMPLE: Concentration of Radionuclide A in Product +

Exempt concentration of Radionuclide A

Concentration of Radionuclide B in Product <1

Exempt concentration of Radionuclide B

NOTE 3: To convert $\mu\text{Ci/ml}$ to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 ($2 \times 10^{-4} \mu\text{Ci/ml}$ multiplied by 37 is equivalent to $74 \times 10^{-4} \text{MBq/l}$)

CHAPTER 39—APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1

Radioactive Material	Microcuries
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10

Radioactive Material	Microcuries
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10

Radioactive Material	Microcuries
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10

Radioactive Material	Microcuries
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

NOTE 1: For purposes of 39.4(25) “f”(5)“2” where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Radionuclide A possessed}}{1000 \times \text{Appendix B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{1000 \times \text{Appendix B quantity for Radionuclide B}} \leq 1$$

NOTE 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

CHAPTER 39—APPENDIX D
LIMITS FOR BROAD LICENSES (39.4(28))

Radioactive Material	Column I curies	Column II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001

Radioactive Material	Column I curies	Column II curies
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1

Radioactive Material	Column I curies	Column II curies
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01

Radioactive Material	Column I curies	Column II curies
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01

Radioactive Material	Column I curies	Column II curies
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.	0.1	0.001

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

CHAPTER 39—APPENDIX E
DETERMINATION OF A_1 AND A_2
Rescinded IAB 4/5/00, effective 5/10/00

CHAPTER 39—APPENDIX F
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY
GUARANTEES FOR PROVIDING REASONABLE ASSURANCE
OF FUNDS FOR DECOMMISSIONING

I. Introduction.

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test.

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; a ratio of current assets to current liabilities greater than 1.5; and

(2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least \$10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, or Baa as issued by Moody's; and

(2) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least \$10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform BRH within 90 days or any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C.1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the BRH of intent to establish alternate financial assurance as specified in BRH rules. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee.

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the BRH. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and BRH, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in BRH rules within 90 days after receipt by the licensee and BRH notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the BRH has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to BRH. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

CHAPTER 39—APPENDIX G

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF
THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (curies)</u>
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
Non CO		
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-173	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (curies)</u>
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-58	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (curies)</u>
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma ²	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha ²	.0001	20
Combinations of radioactive materials listed above ¹	—	—

¹ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Appendix G exceeds one.

² Waste packaged in Type B containers does not require an emergency plan.
[ARC 8982B, IAB 8/11/10, effective 9/15/10]

CHAPTER 39—APPENDIX H
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).
2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).
3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.
2. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
3. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the agency of its intent to establish alternate financial assurance as specified in these rules within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 39—APPENDIX I
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY
COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet the following criteria:

1. Tangible net worth greater than \$10 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

1. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year-end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

2. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send notice to the agency of intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 39—APPENDIX J
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY
NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities to pass the financial test, a college or university must meet either the criteria in Section II.A.1. or the criteria in Section II.A.2. of this appendix.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals to pass the financial test, a hospital must meet either the criteria in Section II.B.1. or the criteria in Section II.B.2. of this appendix:

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long-term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform this agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to this agency of its intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service.

These rules are intended to implement Iowa Code chapter 136C.

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CHAPTER 40
STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

641—40.1(136C) Purpose and scope.

40.1(1) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the agency. These rules are issued pursuant to the authority in Iowa Code section 136C.3 and 136C.4.

40.1(2) The requirements of this chapter are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. However, nothing in this chapter shall be construed as limiting actions that may be necessary to protect health and safety.

40.1(3) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). The term “as low as is reasonably achievable” means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, other societal and socioeconomic considerations, and in relation to the utilization of ionizing radiation in the public interest.

40.1(4) Except as specifically provided in other parts of these rules, this chapter applies to persons licensed or registered by the agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

40.1(5) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of November 5, 2014.

40.1(6) The provisions of Chapter 40 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 45.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.2(136C) Definitions.

40.2(1) For the purposes of this chapter, the definitions of 641—Chapter 38 may also apply.

40.2(2) As used in this chapter, these terms have the definitions set forth below.

“*Annual limit on intake (ALI)*” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

“*Class (or lung class or inhalation class)*” means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days.

“*Declared pregnant woman*” means a woman who has voluntarily informed her licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

“*Derived air concentration (DAC)*” means the concentration of a given radionuclide in air which, if breathed by the reference person for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour) results in an intake of one ALI. DAC values are given in Table I, Column 3, of Appendix B.

“Derived air concentration-hour (DAC-hour)” means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed dose equivalent of 5 rem (0.05 Sv).

“Dosimetry processor” means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

“Inhalation class” (see “Class.”)

“Lung class” (see “Class.”)

“National tracked source” means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of this chapter. In this context a “sealed source” is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

“Nonstochastic effect” means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, “deterministic effect” is an equivalent term.

“Planned special exposure” means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

“Quarter” means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

“Reference person” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference person is contained in the International Commission on Radiological Protection report, ICRP Publication 23, “Report of the Task Group on Reference Man.”

“Respiratory protective equipment” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive materials.

“Sanitary sewerage” means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

“Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, “probabilistic effect” is an equivalent term.

“Weighting factor” w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a0.30 results from 0.06 for each of 5 “remainder” organs, excluding the skin and the lens of the eye, that receive the highest doses.

^bFor the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

641—40.3(136C) Implementation.

40.3(1) Any existing license or registration condition that is more restrictive than this chapter remains in force until there is an amendment or renewal of the license or registration.

40.3(2) If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

40.3(3) If a license or registration condition cites provisions of this chapter in effect prior to January 1, 1994, which do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

641—40.4 to 40.9 Reserved.

RADIATION PROTECTION PROGRAMS

641—40.10(136C) Radiation protection programs.

40.10(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See 40.81(136C) for record-keeping requirements relating to these programs.

40.10(2) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

40.10(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

40.10(4) To implement the ALARA requirements of 40.10(2), and notwithstanding the requirements in 641—40.26(136C), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 641—40.97(136C) and promptly take appropriate corrective action to ensure against recurrence.

641—40.11 to 40.14 Reserved.

OCCUPATIONAL DOSE LIMITS

641—40.15(136C) Occupational dose limits for adults.

40.15(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 40.20(136C), to the following dose limits:

a. An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

b. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

(1) A lens dose equivalent of 15 rem (0.15 Sv), and

(2) A shallow dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

40.15(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 40.20(5) "a" and "b."

40.15(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the agency. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

40.15(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 40.86(136C).

40.15(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

40.15(6) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 40.19(5).

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.16(136C) Compliance with requirements for summation of external and internal doses.

40.16(1) If the licensee or registrant is required to monitor pursuant to both 40.19(1) and 40.19(2), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 40.19(1), or only pursuant to 40.19(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 40.16(2), 40.16(3) and 40.16(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

40.16(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

a. The sum of the fractions of the inhalation ALI for each radionuclide, or

b. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

c. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} , that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

40.16(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

40.16(4) Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subrule.

641—40.17(136C) Determination of external dose from airborne radioactive material.

40.17(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

40.17(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

641—40.18(136C) Determination of internal exposure.

40.18(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 40.37(136C), take suitable and timely measurements of:

- a. Concentrations of radioactive materials in air in work areas; or
- b. Quantities of radionuclides in the body; or
- c. Quantities of radionuclides excreted from the body; or
- d. Combinations of these measurements.

40.18(2) Unless respiratory protective equipment is used, as provided in 40.50(136C), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

40.18(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

- a. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and
- b. Upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
- c. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

40.18(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in 40.8(1) "b" or 40.8(1) "c," the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 40.96(136C) or 40.97(136C). This delay permits the licensee to make additional measurements basic to the assessments.

40.18(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

- a. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

b. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

40.18(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

40.18(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

a. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 40.15(136C) and in complying with the monitoring requirements in 40.37(136C), and

b. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

c. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

40.18(8) When determining the committed effective dose equivalent, the following information may be considered:

a. In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rem (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

b. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in 40.15(1) "a"(2) is met.

641—40.19(136C) Determination of prior occupational dose.

40.19(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to this rule, the licensee or registrant shall:

a. Determine the occupational radiation dose received during the current year; and

b. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

40.19(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

a. The internal and external doses from all previous planned special exposures; and

b. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

c. All lifetime cumulative occupational radiation dose.

40.19(3) In complying with the requirements of 40.19(1), a licensee or registrant may:

a. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

b. Accept, as the record of lifetime cumulative radiation dose, a form signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

c. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

40.19(4) *a.* The licensee or registrant shall record the exposure history, as required by 40.37(136C). The form or record shall show each period in which the individual received occupational exposure to

radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the exposure history. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the report indicating the periods of time for which data are not available.

b. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded on or before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

40.19(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

a. In establishing administrative controls pursuant to 40.15(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

b. That the individual is not available for planned special exposures.

40.19(6) The licensee or registrant shall retain the records in 641—40.19(136C) until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing any record for this subrule for three years after the record is made.

641—40.20(136C) Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 40.15(136C) provided that each of the following conditions is satisfied:

40.20(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

40.20(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

40.20(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

a. Informed of the purpose of the planned operation; and

b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

c. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

40.20(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 40.19(2) during the lifetime of the individual for each individual involved.

40.20(5) Subject to 40.15(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

a. The numerical values of any of the dose limits in 40.15(1) in any year; and

b. Five times the annual dose limits in 40.15(1) during the individual's lifetime.

40.20(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 40.85(136C) and submits a written report in accordance with 40.98(136C).

40.20(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 40.15(1) but shall be included in evaluations required by 40.20(1) and 40.20(2).

641—40.21(136C) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in 40.15(136C).

641—40.22(136C) Dose equivalent to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See 40.86(136C) for record-keeping requirements.

40.22(2) The licensee or registrant shall make efforts to avoid substantial variation¹ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 40.22(1).

40.22(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

- a. The deep dose equivalent to the declared pregnant woman; and
- b. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

40.22(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

¹ The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

641—40.23 to 40.25 Reserved.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

641—40.26(136C) Dose limits for individual members of the public.

40.26(1) Each licensee or registrant shall conduct operations so that:

a. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage under 641—40.72(136C); and

b. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released under 641—subrule 41.2(27), does not exceed 0.002 rem (0.02 millisievert) in any one hour.

40.26(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

40.26(3) A licensee, registrant, or an applicant for a license or registration may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

a. Demonstration of the need for and the expected duration of operations in excess of the limit in 40.26(1); and

b. The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

c. The procedures to be followed to maintain the dose ALARA.

40.26(4) In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

40.26(5) The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

40.26(6) Notwithstanding the requirements of 40.26(1) “a,” a licensee may permit visitors to an individual who cannot be released under 641—subrule 41.2(27) to receive a radiation dose greater than 0.1 rem (1 mSv) if:

- a.* The radiation dose received does not exceed 0.5 rem (5 mSv); and
- b.* The authorized user, as defined in 641—subrule 41.2(2), has determined before the visit that it is appropriate.

641—40.27(136C) Compliance with dose limits for individual members of the public.

40.27(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 40.26(136C).

40.27(2) A licensee or registrant shall show compliance with the annual dose limit in 40.26(136C) by:

a. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

b. Demonstrating that:

(1) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(2) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

40.27(3) Upon approval from the agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

641—40.28(136C) Radiological criteria for license termination.

40.28(1) The criteria in this rule apply to the decommissioning of facilities licensed under 641—Chapter 39, and to the release of part of a facility or site for unrestricted use, as well as other facilities subject to the agency’s jurisdiction under Iowa Code chapter 136C.

40.28(2) The criteria in this rule do not apply to sites which:

a. Have been decommissioned prior to July 1, 1999, in accordance with criteria identified in 641—subrule 39.4(33).

b. Have previously submitted and received agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the United States Nuclear Regulatory Commission (NRC) Site Decommissioning Management Plan (SDMP) Action Plan criteria; or

c. Submit a sufficient LTP or decommissioning plan prior to July 1, 1999, and such LTP or decommissioning plan is approved by the agency prior to July 1, 1999, except that if an environmental impact statement is required in the submittal, there will be a provision for day-to-day extension.

40.28(3) After a site has been decommissioned and the license terminated in accordance with the criteria in this chapter, or after part of a facility or site has been released for unrestricted use in accordance with this chapter, the agency will require additional cleanup only if, based on new information, it determines that the criteria of this chapter were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

40.28(4) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

40.28(5) Public notification and public participation. Upon the receipt of an LTP or decommissioning plan from the licensee or a proposal by the licensee for release of a site pursuant to 40.30(136C) or 40.31(136C) or whenever the agency deems such notice to be in the public interest, the agency shall:

a. Notify and solicit comments from:

(1) Local and state governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to 40.31(136C).

b. Publish a notice in the Iowa Administrative Bulletin and in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

40.28(6) Minimization of contamination. Applicants for licenses, other than renewals, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 641—40.10(136C) and radiological criteria for license termination in 40.28(1) through 40.28(5).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.29(136C) Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

641—40.30(136C) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

40.30(1) The licensee can demonstrate that reductions in residual radioactivity necessary to comply with the provisions of 40.29(136C) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

40.30(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

40.30(3) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

a. Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

b. Rescinded IAB 10/1/14, effective 11/5/14.

c. A statement of intent in the case of federal, state, or local government licensees, as described in 641—subparagraph 39.4(26) “f”(4); or

d. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

40.30(4) The licensee has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33) "d" and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and incorporated, as appropriate, following analysis of that advice. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

a. Whether provisions for institutional controls proposed by the licensee:

(1) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(2) Will be enforceable; and

(3) Will not impose undue burdens on the local community or other affected parties.

b. Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

c. In seeking advice on the issues identified in 40.30(4) "a," the licensee shall provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(2) An opportunity for a comprehensive, collective discussion of the issues by the participants represented; and

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

40.30(5) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

a. 100 mrem (1 mSv) per year; or

b. 500 mrem (5 mSv) per year provided the licensee:

(1) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/yr (1 mSv/yr) value of 40.30(5) "a" are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(2) Makes provisions for durable institutional controls; and

(3) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to ensure that the institutional controls remain in place as necessary to meet the criteria of 40.30(2) and to assume and carry out responsibilities for any necessary controls and maintenance of those controls. Acceptable financial assurance mechanisms are those in subrule 40.30(3).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.31(136C) Alternate criteria for license termination.

40.31(1) The agency may terminate a license using alternate criteria greater than the dose criterion of 641—40.29(136C), 40.30(2) and 40.30(4) "a"(1) if the licensee:

a. Provides assurance that public health and safety would continue to be protected and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 mrem/yr (1 mSv/yr) by submitting an analysis of possible sources of exposure;

b. Has employed, to the extent practical, restrictions on site use according to the provisions of 641—40.30(136C) in minimizing exposures at the site;

c. Reduces doses to ALARA levels taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;

d. Has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33)“*d*,” and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(2) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

e. Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

40.31(2) The use of alternate criteria to terminate a license requires the approval of the agency after consideration of the staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to 40.32(136C).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

641—40.32(136C) Testing for leakage or contamination of sealed sources.

40.32(1) The licensee in possession of any sealed source shall ensure that:

a. Each sealed source, except as specified in 40.32(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.

b. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, after evaluation of information specified by 641—subparagraphs 39.4(29)“*l*”(2) and 39.4(29)“*l*”(3) of these rules, an agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

c. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified by 641—subparagraphs 39.4(29)“*l*”(2) and 39.4(29)“*l*”(3) of these rules, an agreement state, a licensing state, or the Nuclear Regulatory Commission.

d. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall ensure that the sealed source is tested for leakage or contamination before further use.

e. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the “off” position.

f. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 0.001 μCi (37 Bq) of radon-222 in a 24-hour period when the

collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

g. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 0.005 μCi (185 Bq) of a radium daughter which has a half-life greater than four days.

40.32(2) A licensee need not perform tests for leakage or contamination on the following sealed sources:

- a.* Sealed sources containing only radioactive material with a half-life of less than 30 days;
- b.* Sealed sources containing only radioactive material as a gas;
- c.* Sealed sources containing 100 μCi (3.7 MBq) or less of beta- or photon-emitting material or 10 μCi (370 kBq) or less of alpha-emitting material;
- d.* Sealed sources containing only hydrogen-3;
- e.* Seeds of iridium-192 encased in nylon ribbon; and
- f.* Sealed sources, except those used in teletherapy and brachytherapy and those containing radium, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

40.32(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, an agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission to perform such services.

40.32(4) Test results shall be kept in units of microcurie or becquerel and maintained for inspection by the agency.

40.32(5) The following shall be considered evidence that a sealed source is leaking:

- a.* The presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample.
- b.* Leakage of 0.001 μCi (37 Bq) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.
- c.* The presence of removable contamination resulting from the decay of 0.005 μCi (185 Bq) or more of radium.

40.32(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this chapter.

40.32(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 40.102(136C).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.33 to 40.35 Reserved.

SURVEYS AND MONITORING

641—40.36(136C) Surveys and monitoring—general.

40.36(1) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

- a.* Are necessary for the licensee or registrant to comply with this chapter; and
- b.* Are necessary under the circumstances to evaluate:
 - (1) The magnitude and extent of radiation levels; and
 - (2) Concentrations or quantities of residual radioactivity; and
 - (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.

40.36(2) Notwithstanding 641—40.82(136C), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 641—subrule 39.4(26) as applicable.

40.36(3) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable part of these rules or a license condition.

40.36(4) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 40.15(136C), with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

a. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

b. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

40.36(5) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

40.36(6) After replacement, each personnel dosimeter must be sent for processing as soon as possible.

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.37(136C) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. As a minimum:

40.37(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

a. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 40.15(1);

b. Minors likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

c. Individuals entering a high or very high radiation area;

d. Individuals working with medical fluoroscopic equipment; and

e. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv).

40.37(2) Each licensee or registrant shall monitor, to determine compliance with 40.18(136C), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

a. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B;

b. Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

c. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

40.37(3) Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 40.37(136C) wear individual monitoring devices as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded portion of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device shall be near the midline of the body, under the apron;

b. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman shall be located at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 40.15(136C) shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

d. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 40.15(136C), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.38 to 40.41 Reserved.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

641—40.42(136C) Control of access to high radiation areas.

40.42(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

a. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

b. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

c. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

40.42(2) In place of the controls required by 40.42(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

40.42(3) The licensee or registrant may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

40.42(4) The licensee or registrant shall establish the controls required by 40.42(1) and 40.42(3) in a way that does not prevent individuals from leaving a high radiation area.

40.42(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

a. The packages do not remain in the area longer than three days; and

b. The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

40.42(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this chapter and to operate within the ALARA provisions of the licensee's radiation protection program.

40.42(7) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 641—40.42(136C) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.43(136C) Control of access to very high radiation areas.

40.43(1) In addition to the requirements in 40.42(136C), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in 1 hour at 1 meter from a source

of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

40.43(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 40.43(1) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.44(136C) Control of access to very high radiation areas—irradiators.

40.44(1) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

40.44(2) Each area in which there may exist radiation levels in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

a. Each entrance or access point shall be equipped with entry control devices which:

(1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(2) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(3) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in 1 hour.

b. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 40.44(2)“*a*”:

(1) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

c. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source’s shielded storage container:

(1) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

d. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

e. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 40.44(2)“*c*” and 40.44(2)“*d*.”

f. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into

operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

g. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

h. Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour.

i. The entry control devices required in 40.44(2) "a" shall be tested for proper functioning. See 40.89(136C) for record-keeping requirements.

(1) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(3) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

j. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

k. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

40.44(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 40.44(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 40.44(2), such as those for the automatic control of radiation levels, may apply to the agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 40.44(2). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

40.44(4) The entry control devices required by 40.44(2) and 40.44(3) shall be established in such a way that no individual will be prevented from leaving the area.

641—40.45 to 40.47 Reserved.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT
INTERNAL EXPOSURE IN RESTRICTED AREAS

641—40.48(136C) Use of process or other engineering controls. The licensee shall use, to the extent practical, process or other engineering controls, such as containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

641—40.49(136C) Use of other controls.

40.49(1) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- a. Control of access;
- b. Limitation of exposure times;
- c. Use of respiratory protection equipment; or

d. Other controls.

40.49(2) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

641—40.50(136C) Use of individual respiratory protection equipment.

40.50(1) If the licensee assigns or permits the use of respiratory protection equipment to limit intakes pursuant to 40.49(136C):

a. The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH), except as otherwise noted in this subrule.

b. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

c. The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding monitoring, including air sampling and bioassays; supervision and training of respirator user; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; record keeping; and limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment: before the initial fitting of a face-sealing respirator; before the first field use of non-face-sealing respirators; and either every 12 months thereafter, or periodically at a frequency determined by a physician; and

(6) Fit testing, with a fit factor equal to or greater than 10 times the APF for negative pressure devices, and a fit factor equal to or greater than 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight-fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

d. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

e. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

f. Standby rescue persons are required whenever one-piece atmosphere-supplying suits or any combination of supplied air respiratory protection devices and personnel protection equipment is used from which an unaided individual would have difficulty extricating himself or herself. The standby rescue persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication (visual, voice, signal line, telephone, radio, or other suitable means) with the workers, and be immediately available to assist the workers in case of a failure of the air supply or for any

other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

g. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997, and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E)). Grade D quality air criteria include:

- (1) Oxygen content (v/v) of 19.5 to 23.5 percent;
- (2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
- (3) Carbon monoxide (CO) content of 10 ppm or less;
- (4) Carbon dioxide content of 1000 ppm or less; and
- (5) Lack of noticeable odor.

h. The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face, facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

i. In the estimation of the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

40.50(2) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 40.49(136C), provided that the following conditions, in addition to those in 40.50(1), are satisfied:

a. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in 40.49(136C) of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

b. The licensee shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in Appendix A. The agency may authorize a licensee to use higher protection factors on receipt of an application that:

- (1) Describes the situation for which a need exists for higher protection factors, and
- (2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

40.50(3) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

40.50(4) Further restrictions.

a. The licensee shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 40.50(1) or 40.50(2).

b. The agency may impose restrictions in addition to those listed in these rules in order to:

- (1) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

641—40.51 to 40.53 Reserved.

STORAGE AND CONTROL OF LICENSED OR REGISTERED
SOURCES OF RADIATION

641—40.54(136C) Security and control of licensed radioactive material in quantities of concern. Rescinded ARC 1479C, IAB 6/11/14, effective 7/16/14.

641—40.55(136C) Security and control of licensed or registered sources of radiation.

1. The licensee or registrant shall secure licensed or registered radioactive material that is stored in controlled or unrestricted areas from unauthorized removal or access.

2. The licensee or registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

3. The registrant shall secure registered radiation machines from unauthorized removal.

4. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

5. Security requirements for portable gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

641—40.56(136C) Control of sources of radiation not in storage. Rescinded IAB 4/8/98, effective 7/1/98.

641—40.57 to 40.59 Reserved.

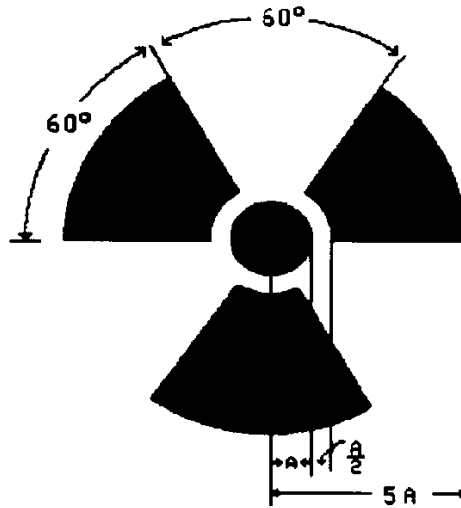
PRECAUTIONARY PROCEDURES

641—40.60(136C) Caution signs.

40.60(1) Standard radiation symbol. Unless otherwise authorized by the agency, the symbol prescribed by this rule shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



40.60(2) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of 40.60(1), licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

40.60(3) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

40.60(4) Improper posting or labeling. The licensee or registrant shall ensure that adequate measures are taken to prevent improper posting or labeling.

641—40.61(136C) Posting requirements.

40.61(1) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIATION AREA”.

40.61(2) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA”.

40.61(3) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words “GRAVE DANGER, VERY HIGH RADIATION AREA”.

40.61(4) Posting of airborne radioactivity areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, AIRBORNE RADIOACTIVITY AREA” or “DANGER, AIRBORNE RADIOACTIVITY AREA”.

40.61(5) Posting of areas or rooms in which licensed or registered material is used or stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL(S)” or “DANGER, RADIOACTIVE MATERIAL(S)”.

641—40.62(136C) Exceptions to posting requirements.

40.62(1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

a. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

b. The area or room is subject to the licensee's or registrant's control.

40.62(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 40.61(136C) provided that the patient could be released from licensee control pursuant to 641—subrule 41.2(27).

40.62(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

40.62(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis or simulation in the healing arts.

40.62(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 641—40.61(136C) if:

a. Access to the room is controlled pursuant to 641—subrule 41.2(53); and

b. Personnel in attendance take necessary precautions to prevent an inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

641—40.63(136C) Labeling containers and radiation machines.

40.63(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

40.63(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

40.63(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

641—40.64(136C) Exemptions to labeling requirements. A licensee is not required to label:

40.64(1) Containers holding licensed materials in quantities less than the quantities listed in Appendix C; or

40.64(2) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

40.64(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter; or

40.64(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation;¹ or

40.64(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

40.64(6) Installed manufacturing or process equipment, such as piping and tanks.

¹ Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

641—40.65(136C) Procedures for receiving and opening packages.

40.65(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity shall make arrangements to receive:

- a. The package when the carrier offers it for delivery; or
- b. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

40.65(2) Each licensee shall:

- a. Monitor the external surfaces of a labeled¹ package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 641—Chapter 38;
- b. Monitor the external surfaces of a labeled¹ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity; and
- c. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

40.65(3) The licensee shall perform the monitoring required by 40.65(2) as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

40.65(4) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the agency when:

- a. Removable radioactive surface contamination exceeds the limits of 49 CFR 173.443; or
- b. External radiation levels exceed the limits of 10 CFR 71.47 as set forth in rule 641—39.5(136C).

40.65(5) Each licensee shall:

- a. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
- b. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

40.65(6) Licensees transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of 40.65(2), but are not exempt from the monitoring requirement in 40.65(2), for measuring radiation levels that ensure that the source is still properly lodged in its shield.

¹ Labeled with a Radioactive e White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

641—40.66 to 40.69 Reserved.

WASTE DISPOSAL

641—40.70(136C) General requirements.

40.70(1) A licensee shall dispose of licensed material only:

- a. By transfer to an authorized recipient as provided in 40.74(136C) or 641—39.4(136C), or to the U.S. Department of Energy; or
- b. By decay in storage; or
- c. By release in effluents within the limits in 40.72(1) "d"; or
- d. As authorized pursuant to 641—40.71(136C), 641—40.72(136C), 641—40.73(136C), 641—40.74(136C), or 641—40.77(136C).

40.70(2) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

- a. Treatment prior to disposal; or
- b. Treatment or disposal by incineration; or
- c. Decay in storage; or
- d. Storage until transferred to a storage or disposal facility authorized to receive the waste.

641—40.71(136C) Method for obtaining approval of proposed disposal procedures. A licensee or applicant for a license may apply to the agency for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

40.71(1) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

40.71(2) An analysis and evaluation of pertinent information on the nature of the environment; and

40.71(3) The nature and location of other potentially affected facilities; and

40.71(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this chapter.

641—40.72(136C) Disposal by release into sanitary sewerage.

40.72(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

a. The material is readily soluble, or is readily dispersible biological material, in water; and

b. The quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and

c. If more than one radionuclide is released, the following conditions must also be satisfied:

(1) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(2) The sum of the fractions for each radionuclide required by 40.72(1) "c"(1) does not exceed unity; and

d. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 Ci (185 GBq) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

40.72(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 40.72(1).

641—40.73(136C) Treatment or disposal by incineration. A licensee may treat or dispose of licensed materials by incineration only in the amounts and forms specified in 40.74(136C) or as specifically approved by the agency pursuant to 40.71(136C).

641—40.74(136C) Disposal of specific wastes.

40.74(1) A licensee may dispose of the following licensed material as if it were not radioactive:

a. 0.05 μ Ci (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

b. 0.05 μ Ci (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

40.74(2) A licensee shall not dispose of tissue pursuant to 40.74(1) "b" in a manner that would permit its use either as food for humans or as animal feed.

40.74(3) The licensee shall maintain records in accordance with 40.88(136C).

641—40.75(136C) Transfer for disposal and manifests.

40.75(1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

40.75(2) Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix D of this chapter.

40.75(3) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D of this chapter.

40.75(4) Any licensee shipping licensed material, as defined in paragraphs “3” and “4” of the definition of “by-product material” set forth in 641—Chapter 38, intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.76(136C) Compliance with environmental and health protection regulations. Nothing in 40.70(136C), 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), or 40.75(136C) relieves the licensee or registrant from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 40.70(136C), 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), or 40.75(136C).

641—40.77(136C) Disposal of certain by-product material.

40.77(1) Licensed material, as defined in paragraphs “3” and “4” of the definition of “by-product material” set forth in 641—Chapter 38, may be disposed of in accordance with 10 CFR Part 61, even though the material is not defined as low-level radioactive waste. Therefore, any licensed by-product material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirements of 641—40.75(136C).

40.77(2) A licensee may dispose of licensed material, as defined in paragraphs “3” and “4” of the definition of “by-product material” set forth in 641—Chapter 38, at a disposal facility authorized to dispose of such material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.78 and 40.79 Reserved.

RECORDS

641—40.80(136C) General provisions.

40.80(1) Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

40.80(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

40.80(3) In the records required by this chapter, the licensee may record quantities in SI units in parentheses following each of the units specified in 40.80(1). However, all quantities must be recorded as stated in 40.80(1).

40.80(4) Notwithstanding the requirements of 40.80(1), when recording information on shipment manifests, as required in 641—40.75(136C), information must be recorded in the International System of Units (SI) or in SI and units as specified in 40.80(1).

40.80(5) Notwithstanding the requirements of 40.80(1), records of removable radioactive surface contamination on packages shall be recorded in disintegrations per minute (dpm).

641—40.81(136C) Records of radiation protection programs.

40.81(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

- a.* The provisions of the program; and
- b.* Audits and other reviews of program content and implementation.

40.81(2) The licensee or registrant shall retain the records required by 40.81(1) “*a*” until the agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 40.81(1) “*b*” for three years after the record is made.

641—40.82(136C) Records of surveys.

40.82(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 40.36(136C) and 40.65(2). The licensee or registrant shall retain these records for three years after the record is made.

40.82(2) The licensee or registrant shall retain each of the following records until the agency terminates each pertinent license or registration requiring the record:

- a.* Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and
- b.* Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
- c.* Records showing the results of air sampling, surveys, and bioassays required pursuant to 40.50(1) “*c*”(1) and 40.50(1) “*c*”(2); and
- d.* Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

40.82(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 641—40.82(136C) or shall make provisions with the agency for transfer to the agency.

641—40.83(136C) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by 40.32(136C) shall be kept in units of microcurie or becquerel and maintained for inspection by the agency for five years after the records are made.

641—40.84(136C) Records of prior occupational dose.

40.84(1) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 40.19(136C) until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the record required in 40.84(136C) for three years after the record is made.

40.84(2) Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 40.84(136C) or shall make provisions with the agency for transfer to the agency.

641—40.85(136C) Records of planned special exposures.

40.85(1) For each use of the provisions of 40.20(136C) for planned special exposures, the licensee or registrant shall maintain records that describe:

- a.* The exceptional circumstances requiring the use of a planned special exposure; and
- b.* The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
- c.* What actions were necessary; and
- d.* Why the actions were necessary; and
- e.* What precautions were taken to assure that doses were maintained ALARA; and
- f.* What individual and collective doses were expected to result; and
- g.* The doses actually received in the planned special exposure.

40.85(2) The licensee or registrant shall retain the records until the agency terminates each pertinent license or registration requiring these records.

40.85(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 40.85(136C) or shall make provisions with the agency for transfer to the agency.

641—40.86(136C) Records of individual monitoring results.

40.86(1) *Record-keeping requirement.* Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 40.37(136C), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect on or before January 1, 1994, need not be changed. These records shall include, when applicable:

- a. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
- b. The estimated intake of radionuclides, see 40.16(136C); and
- c. The committed effective dose equivalent assigned to the intake of radionuclides; and
- d. The specific information used to calculate the committed effective dose equivalent pursuant to 40.18(3); and
- e. The total effective dose equivalent when required by 40.16(136C); and
- f. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

40.86(2) *Record-keeping frequency.* The licensee or registrant shall make entries of the records specified in 40.86(1) at intervals not to exceed one year.

40.86(3) *Record-keeping format.* The licensee or registrant shall maintain the records specified in 40.86(1) in clear and legible form.

40.86(4) *Embryo/Fetus records.* The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

40.86(5) *Retention during license or registration.* The licensee or registrant shall retain each required form or record until the agency terminates each pertinent license or registration requiring the record.

40.86(6) *Retention after termination.* Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 40.86(136C) or shall make provision with the agency for transfer to the agency.

641—40.87(136C) Records of dose to individual members of the public.

40.87(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 40.26(136C).

40.87(2) The licensee or registrant shall retain the records required by this rule until the agency terminates each pertinent license or registration requiring the record.

641—40.88(136C) Records of waste disposal.

40.88(1) Each licensee shall maintain records of the disposal of licensed materials made pursuant to 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), and disposal or burial in soil.

40.88(2) The licensee shall retain the records required by 40.88(1) until the agency terminates each pertinent license or registration requiring the record.

641—40.89(136C) Records of testing entry control devices for very high radiation areas.

40.89(1) Each licensee or registrant shall maintain records of tests made pursuant to 40.44(2) “j” on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

40.89(2) The licensee or registrant shall retain the records required by 40.89(1) for three years after the record is made.

641—40.90(136C) Form of records.

40.90(1) Each record required by Chapter 40 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period, or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

40.90(2) The licensee or registrant shall retain the records required by Chapter 40 until the agency terminates each pertinent license or registration requiring the record.

641—40.91 to 40.94 Reserved.

REPORTS

641—40.95(136C) Reports of stolen, lost, or missing licensed or registered sources of radiation.

40.95(1) Telephone reports. Each licensee or registrant shall report to the agency by telephone as follows:

a. Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

b. Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in quantity greater than ten times the quantity specified in Appendix C that is still missing.

c. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

d. Rescinded IAB 3/30/05, effective 5/4/05.

40.95(2) Written reports. Each licensee or registrant required to make a report pursuant to 40.95(1) shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

a. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

b. A description of the circumstances under which the loss or theft occurred; and

c. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

d. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

e. Actions that have been taken, or will be taken, to recover the source of radiation; and

f. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

40.95(3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

40.95(4) The licensee or registrant shall prepare any report filed with the agency pursuant to 40.95(136C) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

641—40.96(136C) Notification of incidents.

40.96(1) Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

a. An individual to receive:

- (1) A total effective dose equivalent of 25 rem (0.25 Sv) or more; or
- (2) A lens dose equivalent of 75 rem (0.75 Sv) or more; or
- (3) A shallow dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more; or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. In addition to the requirements of paragraphs “*a*” and “*b*” above, each licensee shall notify the Iowa department of public health as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, and other such events).

40.96(2) Twenty-four-hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

a. An individual to receive, in a period of 24 hours:

- (1) A total effective dose equivalent exceeding 5 rem (0.05 Sv); or
- (2) A lens dose equivalent exceeding 15 rem (0.15 Sv); or
- (3) A shallow dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv); or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. In addition to the requirements of paragraphs “*a*” and “*b*” above, each licensee shall notify the Iowa department of public health within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B for the material; and

3. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

2. The equipment is required to be available and operable when it is disabled or fails to function; and

3. No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual’s clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

1. The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B for the material; and

2. The damage affects the integrity of the licensed material or its container.

40.96(3) The licensee or registrant shall prepare each report filed with the agency pursuant to 40.96(136C) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

40.96(4) Licensees or registrants shall make the reports required by 40.96(1) and 40.96(2) to the agency by telephone, telegram, mailgram, or facsimile.

a. Licensees or registrants making initial reports to the Iowa department of public health shall to the extent that the information is available at the time of notification include:

- (1) The caller's name and call-back telephone number;
- (2) A description of the event, including date and time;
- (3) The exact location of the event;
- (4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (5) Any personnel radiation exposure data available.

b. Each licensee or registrant who makes a report required by 40.96(1) or 40.96(2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information. These written reports must be sent to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319. The reports must include the following:

- (1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (2) The exact location of the event;
- (3) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (4) Date and time of the event;
- (5) Corrective actions taken or planned and the results of any evaluations or assessments; and
- (6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

40.96(5) The provisions of 641—40.96(136C) do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 641—40.98(136C).

641—40.97(136C) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

40.97(1) Reportable events. In addition to the notification required by 40.96(136C), each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

a. Incidents for which notification is required by 40.96(136C); or

b. Doses in excess of any of the following:

- (1) The occupational dose limits for adults in 40.15(136C); or
- (2) The occupational dose limits for a minor in 40.21(136C); or
- (3) The limits for an individual member of the public in 40.26(136C); or
- (4) Any applicable limit in the license or registration; or
- (5) The ALARA constraints for air emissions established under 641—40.10(136C); or
- (6) The limits for an embryo/fetus of a declared pregnant woman in 40.22(136C).

c. Levels of radiation or concentrations of radioactive material in:

- (1) A restricted area in excess of applicable limits in the license or registration; or
- (2) An unrestricted area in excess of ten times the applicable limit set forth in this chapter or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 40.26(136C); or

d. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

40.97(2) Contents of reports.

a. Each report required by 40.97(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

- (1) Estimates of each individual's dose; and
- (2) The levels of radiation and concentrations of radioactive material involved; and
- (3) The cause of the elevated exposures, dose rates, or concentrations; and
- (4) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

Each report filed pursuant to this paragraph must include the name, social security number, and date of birth for each occupationally overexposed individual. The report must be prepared so that this information is stated in a separate and detachable part of the report.

b. Each report filed pursuant to 40.97(1) shall include for each individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus in 40.22(136C), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

40.97(3) All licensees or registrants who make reports pursuant to 641—40.97(136C) or 641—40.98(136C) to the agency regarding exposure of an identified occupationally exposed individual, or of an identified member of the public, to radiation or radioactive material shall also provide a copy of the report to the individual or member of the public. Transmittal shall be at the same time as the transmittal to the agency.

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641—40.98(136C) Reports of planned special exposures. The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with 40.20(136C) informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 40.85(136C).

641—40.99(136C) Reports of transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subrules 40.99(1) to 40.99(5) for each type of transaction.

40.99(1) Each licensee that manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The manufacturer, model, and serial number of the source;
- d.* The radioactive material in the source;
- e.* The initial source strength in becquerels (curies) at the time of manufacture; and
- f.* The manufacture date of the source.

40.99(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The name and license number of the recipient facility and the shipping address;
- d.* The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- e.* The radioactive material in the source;
- f.* The initial or current source strength in becquerels (curies);
- g.* The date for which the source strength is reported;
- h.* The shipping date;
- i.* The estimated arrival date; and

j. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

40.99(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The name, address, and license number of the person that provided the source;
- d.* The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- e.* The radioactive material in the source;
- f.* The initial or current source strength in becquerels (curies);
- g.* The date for which the source strength is reported;
- h.* The date of receipt; and
- i.* For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

40.99(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- d.* The radioactive material in the source;
- e.* The initial or current source strength in becquerels (curies);
- f.* The date for which the source strength is reported; and
- g.* The disassemble date of the source.

40.99(5) Each licensee that disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The waste manifest number;
- d.* The container identification with the nationally tracked source;
- e.* The date of disposal; and
- f.* The method of disposal.

40.99(6) Reports discussed in subrules 40.99(1) to 40.99(5) must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

- a.* The on-line National Source Tracking System;
- b.* Electronically using a computer-readable format;
- c.* By facsimile;
- d.* By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or
- e.* By telephone with follow-up by facsimile or mail.

40.99(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subrules 40.99(1) to 40.99(5). By January 31 of each

year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

40.99(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified in subrule 40.99(6). The initial inventory report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
- d.* The radioactive material in the sealed source;
- e.* The initial or current source strength in becquerels (curies); and
- f.* The date for which the source strength is reported.

641—40.100(136C) Reports of individual monitoring.

40.100(1) This section applies to each person licensed or registered by the agency to:

- a.* Possess or use sources of radiation for purposes of industrial radiography pursuant to 641—39.4(136C) and 641—Chapter 45; or
- b.* Receive radioactive waste from other persons for disposal pursuant to 10 CFR Part 61 of federal regulations or appropriate other agreement state regulations; or
- c.* Possess or use at any time, for processing or manufacturing for distribution pursuant to 641—39.4(136C) or 641—41.2(136C), radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity ^a	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

^a The agency may require as a license condition, or by rule, regulation, or order pursuant to 40.105(136C), reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

40.100(2) Each licensee or registrant in a category listed in 40.100(1) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 40.36(136C) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required.

40.100(3) The licensee or registrant shall file the report required by 40.100(2), covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the agency.

641—40.101(136C) Notifications and reports to individuals.

40.101(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 641—40.112(136C).

40.101(2) When a licensee or registrant is required pursuant to 40.97(136C), 40.98(136C), or 40.100(136C) to report to the agency any exposure of an identified occupationally exposed individual,

or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to this agency to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of 40.112(1).

641—40.102(136C) Reports of leaking or contaminated sealed sources. The licensee shall file a report within five days with the agency if the test for leakage or contamination required pursuant to 40.32(136C) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

641—40.103 and 40.104 Reserved.

ADDITIONAL REQUIREMENTS

641—40.105(136C) Vacating premises. Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of their activities, notify the agency in writing of intent to vacate. When deemed necessary by the agency, the licensee shall decontaminate the premises in such a manner as the agency may specify.

641—40.106 to 40.109 Reserved.

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

641—40.110(136C) Posting of notices to workers.

40.110(1) Each licensee or registrant, except those registrants with diagnostic X-ray systems, shall post current copies of the following documents:

- a.* This subrule and 641—Chapter 40;
- b.* The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
- c.* The operating procedures applicable to activities under the license or registration; and
- d.* Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 641—Chapter 38, and any response from the licensee or registrant.

40.110(2) If posting of a document specified in 40.110(1) “*a*,” 40.110(1) “*b*” and 40.110(1) “*c*” is not practical, the licensee or registrant may post a notice which describes the document and states where it may be examined.

40.110(3) Agency Form “Notice to Employees” shall be posted by each licensee or registrant.

40.110(4) Agency documents posted pursuant to 40.110(1) “*d*” shall be posted within two working days after receipt of the documents from the agency; the licensee’s or registrant’s response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

40.110(5) Documents, notices, or forms posted pursuant to 40.110(1) shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

641—40.111(136C) Instructions to workers.

40.111(1) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv):

- a.* Shall be kept informed of the storage, transfer, or use of sources of radiation;

b. Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

c. Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

d. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these rules, and licenses or unnecessary exposure to radiation or radioactive material;

e. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

f. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 641—40.112(136C).

g. The instruction in “*b*” through “*f*” above shall be conducted at least annually.

h. Shall be commensurate with potential radiological health protection problems present in the workplace.

40.111(2) In determining those individuals subject to the requirements of 40.111(1), consideration must be given to assigning activities during normal and abnormal situations involving exposure to sources of radiation which can reasonably be expected to occur during the life of the facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

641—40.112(136C) Notifications and reports to individuals.

40.112(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in subrule 40.112(2). The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 40.86(136C). Each notification and report shall:

a. Be in writing;

b. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

c. Include the individual's exposure information; and

d. Contain the following statement:

“This report is furnished to you under the provisions of 40.112(136C) of Iowa's Radiation Machine and Radioactive Materials rules. You should preserve this report for further reference.”

40.112(2) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of 641—40.86(136C). The licensee or registrant shall provide to each individual monitored under 641—40.37(136C) an annual report of the dose received in that monitoring year if:

a. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue, or

b. The individual requests the individual's annual dose report.

40.112(3) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to 40.37(136C). Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

40.112(4) When a licensee or registrant is required pursuant to 641—40.96(136C), 641—40.97(136C), or 641—40.98(136C) to report to the agency any exposure of an individual to

radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the individual's exposure data included in the report to the agency. Such reports shall be transmitted at a time not later than the transmittal to the agency.

40.112(5) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

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641—40.113(136C) Presence of representatives of licensees or registrants and workers during inspection.

40.113(1) Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

40.113(2) During an inspection, agency inspectors may consult privately with workers as specified in 40.114(136C). The licensee or registrant may accompany agency inspectors during other phases of an inspection.

40.113(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

40.113(4) Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 40.111(136C).

40.113(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspectors.

40.113(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

40.113(7) Notwithstanding the other provisions of 40.113(136C), agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

641—40.114(136C) Consultation with workers during inspections.

40.114(1) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

40.114(2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these rules, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 40.115(1).

40.114(3) The provisions of 40.114(2) shall not be interpreted as authorization to disregard instructions pursuant to 40.111(136C).

641—40.115(136C) Requests by workers for inspections.

40.115(1) Any worker or representative of workers believing that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Bureau of Radiological Health, no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

40.115(2) If, upon receipt of such notice, the Bureau of Radiological Health determines that the complaint meets the requirements set forth in 40.116(1), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to 40.116(136C) need not be limited to matters referred to in the complaint.

40.115(3) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this chapter.

641—40.116(136C) Inspections not warranted—informal review.

40.116(1) a. If the Bureau of Radiological Health determines, with respect to a complaint under this rule, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Bureau of Radiological Health shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Attorney General's Office. Such agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Attorney General's Office. Such agency will provide the complainant with a copy of such statement by certified mail.

b. Upon the request of the complainant, the Attorney General's Office may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Attorney General's Office shall affirm, modify, or reverse the determination of the Radiation Control Program and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

40.116(2) If the Bureau of Radiological Health determines that an inspection is not warranted because the requirements of 40.116(1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 40.116(1).

641—40.117(136C) Employee protection.

40.117(1) Discrimination by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in 641—Chapters 38 to 45 and in general are related to the administration or enforcement of requirements imposed under 641—Chapters 38 to 45.

a. The protected activities include but are not limited to:

(1) Providing the agency or the individual's employer information about alleged violations of either of the statutes named in this rule or possible violations of requirements imposed under either of those statutes;

(2) Refusing to engage in any practice made unlawful under either of the statutes named in this rule or under these requirements if the employee has identified the alleged illegality to the employer;

(3) Requesting that the agency institute action against the individual's employer for the administration or enforcement of these requirements;

(4) Testifying in any agency proceeding, or before Congress, or at any federal or state proceeding regarding any provision (or proposed provision) of federal statutes or these rules;

(5) Assisting or participating in, or about to assist or participate in, these activities.

b. These activities are protected even if no formal proceeding is actually initiated as a result of the employee's assistance or participation.

c. This rule has no application to any employee alleging discrimination prohibited by this rule who, acting without direction from the individual's employer (or the employer's agent), deliberately causes a violation of any requirement of 641—Chapters 38 to 45.

40.117(2) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in 40.117(1)“a” may seek a remedy for the discharge or discrimination through an administrative proceeding in the U.S. Department of Labor. The administration proceeding must be initiated within 180 days after an alleged violation occurs. The employee may file for the administrative proceeding by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

40.117(3) A violation of 40.117(1)“a”(1) or 40.117(1)“a”(4) by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant may be grounds for:

a. Denial, revocation, or suspension of the license or registration.

b. Imposition of a civil penalty on the licensee, registrant, or applicant.

c. Other enforcement action.

40.117(4) Actions taken by an employer or others which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render the employee immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

40.117(5) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to 641—Chapters 38 to 45, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in 40.117(1)“a” including, but not limited to, providing information to the agency or to the individual's employer on potential violations or other matters within the agency's regulatory responsibilities.

CHAPTER 40

APPENDIX A

PROTECTION FACTORS FOR RESPIRATORS^a

	Operating Mode	Assigned Protection Factor
I. Air-Purifying Respirators (particulate 1A ^b only) 1A ^c :		
Filtering facepiece disposable ^d	Negative Pressure	(^d)
Facepiece, half ^e	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere-Supplying Respirators (particulate, gases and vapors 1A ^f):		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	(^g)
2. Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	^h 100
Facepiece, full	Pressure Demand	ⁱ 10,000
Facepiece, full	Demand, Recirculating	^h 100
Facepiece, full	Positive Pressure Recirculating	ⁱ 10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	(1) Assigned protection factor for type and mode of operation as listed above	

^aThese assigned protection factors apply only in a respiratory protection program that meets the requirement of 641—Chapter 40. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table I, Column 3, of Appendix B to 641—Chapter 40 are based on internal dose due to inhalation may, in addition, present external exposure

hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

^bAir-purifying respirators with APF<100 must be equipped with particulate filters that are at least 95 percent efficient. Air-purifying respirators with APF=100 must be equipped with particulate filters that are at least 99 percent efficient. Air-purifying respirators with APF>100 must be equipped with particulate filters that are at least 99.97 percent efficient.

^cThe licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

^dLicensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for the use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 641—40.50(136C) apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

^eUnder-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient, and all other requirements of 641—Chapter 40 are met.

^fThe assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

^gNo NIOSH approval schedule is currently available for atmosphere-supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met.

^hThe licensee should implement institutional controls to ensure that these devices are not used in areas immediately dangerous to life or health.

ⁱThis type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

CHAPTER 40

APPENDIX B

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS
(DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT
CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μ m, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

NOTE: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^2 or 600, and 6E+0 represents 6×10^0 or 6.

TABLE I "OCCUPATIONAL VALUES"

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Person" which would result in either (1) a committed effective dose equivalent of 5 rem (0.05 Sv), stochastic ALI, or (2) a committed dose equivalent of 50 rem (0.5 Sv) to an organ or tissue, nonstochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rem (0.05 Sv). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T . This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in 40.2. The nonstochastic ALIs were derived to avoid nonstochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract—stomach, small intestine, upper large intestine, and lower large intestine—are to be treated as four separate organs.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 (ml), relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5 rem (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall	=	lower large intestine wall;
St. wall	=	stomach wall;
Blad wall	=	bladder wall; and
Bone surf	=	bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and nonstochastic ALIs, will ensure that nonstochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the nonstochastic ALI is limiting, use of that nonstochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50 rem (0.5 Sv) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, Σ (intake (in μCi) of each radionuclide/ ALI_{ns}) ≤ 1.0 . If there is an external deep dose equivalent contribution of H_d , then this sum must be less than $1 - (H_d/50)$, instead of ≤ 1.0 .

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$$DAC = ALI(\text{in } \mu\text{Ci}) / (2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute}) = [ALI / 2.4 \times 10^9] \mu\text{Ci/ml}$$
, where 2×10^4 ml is the volume of air breathed per minute at work by Reference Person under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 641—40.16(136C). When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

TABLE II “EFFLUENT CONCENTRATIONS”

The columns in Table II of this appendix captioned “Effluents,” “Air” and “Water” are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 641—40.27(136C). The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (0.5 mSv).

Consideration of nonstochastic limits has not been included in deriving the air and water effluent concentration limits because nonstochastic effects are presumed not to occur at or below the dose levels

established for individual members of the public. For radionuclides, where the nonstochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as they were in Appendix A of this chapter of the eighth edition of Volume I of the Suggested State Regulations for Control of Radiation.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 (ml), relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5 rem (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7 . The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of Reference Person.

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

TABLE III "RELEASES TO SEWERS"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 40.72. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by Reference Person, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Person during a year, would result in a committed effective dose equivalent of 0.5 rem.

LIST OF ELEMENTS

Atomic			Atomic		
<u>Name</u>	<u>Symbol</u>	<u>Number</u>	<u>Name</u>	<u>Symbol</u>	<u>Number</u>
Actinium	Ac	89	Mercury	Hg	80
Aluminum	Al	13	Molybdenum	Mo	42
Americium	Am	95	Neodymium	Nd	60
Antimony	Sb	51	Neptunium	Np	93
Argon	Ar	18	Nickel	Ni	28
Arsenic	As	33	Niobium	Nb	41
Astatine	At	85	Nitrogen	N	7
Barium	Ba	56	Osmium	Os	76
Berkelium	Bk	97	Oxygen	O	8
Beryllium	Be	4	Palladium	Pd	46
Bismuth	Bi	83	Phosphorus	P	15

Bromine	Br	35	Platinum	Pt	78
Cadmium	Cd	48	Plutonium	Pu	94
Calcium	Ca	20	Polonium	Po	84
Californium	Cf	98	Potassium	K	19
Carbon	C	6	Praseodymium	Pr	59
Cerium	Ce	58	Promethium	Pm	61
Cesium	Cs	55	Protactinium	Pa	91
Chlorine	Cl	17	Radium	Ra	88
Chromium	Cr	24	Radon	Rn	86
Cobalt	Co	27	Rhenium	Re	75
Copper	Cu	29	Rhodium	Rh	45
Curium	Cm	96	Rubidium	Rb	37
Dysprosium	Dy	66	Ruthenium	Ru	44
Einsteinium	Es	99	Samarium	Sm	62
Erbium	Er	68	Scandium	Sc	21
Europium	Eu	63	Selenium	Se	34
Fermium	Fm	100	Silicon	Si	14
Fluorine	F	9	Silver	Ag	47
Francium	Fr	87	Sodium	Na	11
Gadolinium	Gd	64	Strontium	Sr	38
Gallium	Ga	31	Sulfur	S	16
Germanium	Ge	32	Tantalum	Ta	73
Gold	Au	79	Technetium	Tc	43
Hafnium	Hf	72	Tellurium	Te	52
Holmium	Ho	67	Terbium	Tb	65
Hydrogen	H	1	Thallium	Tl	81
Indium	In	49	Thorium	Th	90
Iodine	I	53	Thulium	Tm	69
Iridium	Ir	77	Tin	Sn	50
Iron	Fe	26	Titanium	Ti	22
Krypton	Kr	36	Tungsten	W	74
Lanthanum	La	57	Uranium	U	92
Lead	Pb	82	Vanadium	V	23
Lutetium	Lu	71	Xenon	Xe	54
Magnesium	Mg	12	Ytterbium	Yb	70
Manganese	Mn	25	Yttrium	Y	39
Mendelevium	Md	101	Zinc	Zn	30
			Zirconium	Zr	40

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
Gas (HT or T ₂) Submersion ¹ : Use above values as HT and T ₂ oxidize in air and in the body to HTO.								
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ⁷ Be	1E+3 LLI wall	2E+2	6E-8	2E-10	-	-
			(1E+3)	-	-	-	2E-5	2E-4
		Y, see ⁷ Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11 ²	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
8	Oxygen-15 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
9	Fluorine-18 ²	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
		St wall	(5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re		9E+4	4E-5	1E-7	-	-
		Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	DAC (μCi/ml)			
14 Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
	Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14 Silicon-32	D, see ³¹ Si	2E+3	2E+2	1E-7	3E-10	-	-
	LLI wall	(3E+3)	-	-	-	4E-5	4E-4
	W, see ³¹ Si	-	1E+2	5E-8	2E-10	-	-
	Y, see ³¹ Si	-	5E+0	2E-9	7E-12	-	-
15 Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
	W, phosphates of Zn ²⁺ , S ³⁺ , Mg ²⁺ , Fe ³⁺ , Bi ³⁺ , and lanthanides	-	4E+2	2E-7	5E-10	-	-
15 Phosphorus-33	D, see ³² P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
	W, see ³² P	-	3E+3	1E-6	4E-9	-	-
16 Sulfur-35	Vapor	-	1E+4	6E-6	2E-8	-	-
	D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
	LLI wall	(8E+3)	-	-	-	1E-4	1E-3
	W, elemental sulfur,	6E+3					
	sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	-	2E+3	9E-7	3E-9	-	-
17 Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio-nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
17	Chlorine-38 ²	D, see ³⁶ Cl	2E+4	4E+4	2E-5	6E-8	-
		St wall	(3E+4)	-	-	3E-4	3E-3
		W, see ³⁶ Cl	-	5E+4	2E-5	6E-8	-
17	Chlorine-39 ²	D, see ³⁶ Cl	2E+4	5E+4	2E-5	7E-8	-
		St wall	(4E+4)	-	-	5E-4	5E-3
		W, see ³⁶ Cl	-	6E+4	2E-5	8E-8	-
18	Argon-37	Submersion ¹	-	-	1E+0	6E-3	-
18	Argon-39	Submersion ¹	-	-	2E-4	8E-7	-
18	Argon-41	Submersion ¹	-	-	3E-6	1E-8	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-4
19	Potassium-44 ²	D, all compounds	2E+4	7E+4	3E-5	9E-8	-
		St wall	(4E+4)	-	-	5E-4	5E-3
19	Potassium-45 ²	D, all compounds	3E+4	1E+5	5E-5	2E-7	-
		St wall	(5E+4)	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-
		Bone surf	(4E+3)	(4E+3)	-	5E-9	6E-5
						6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-
		LLI wall	(3E+3)	-	-	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5
21	Scandium-49 ²	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6
		W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-
		Y, SrTiO	-	6E+0	2E-9	8E-12	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
22	Titanium-45	D, see ⁴⁴ Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ⁴⁴ Ti	-	4E+4	1E-5	5E-8	-	-
		Y, see ⁴⁴ Ti	-	3E+4	1E-5	4E-8	-	-
23	Vanadium-47 ²	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
		St wall	(3E+4)	-	-	-	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23	Vanadium-48	D, see ⁴⁷ V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see ⁴⁷ V	-	6E+2	3E-7	9E-10	-	-
23	Vanadium-49	D, see ⁴⁷ V	7E+4	3E+4	1E-5	-	-	-
		LLI wall	(9E+4)	(3E+4)	-	5E-8	1E-3	1E-2
		W, see ⁴⁷ V	-	2E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49 ²	D, see ⁴⁸ Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ⁴⁸ Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see ⁴⁸ Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see ⁴⁸ Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ⁴⁸ Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see ⁴⁸ Cr	-	2E+4	8E-6	3E-8	-	-
25	Manganese-51 ²	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-
		D, see ⁵¹ Mn	3E+4	9E+4	4E-5	1E-7	-	-
25	Manganese-52m ²	St wall	(4E+4)	-	-	-	5E-4	5E-3
		W, see ⁵¹ Mn	-	1E+5	4E-5	1E-7	-	-
		D, see ⁵¹ Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
25	Manganese-52	W, see ⁵¹ Mn	-	9E+2	4E-7	1E-9	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
25	Manganese-53	D, see ⁵¹ Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
				Bone surf				
			-	(2E+4)	-	3E-8	-	-
		W, see ⁵¹ Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see ⁵¹ Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ⁵¹ Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see ⁵¹ Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ⁵¹ Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see ⁵² Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ⁵² Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see ⁵² Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ⁵² Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see ⁵² Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ⁵² Fe	-	2E+1	8E-9	3E-11	-	-
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
27	Cobalt-56	W, see ⁵⁵ Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ⁵⁵ Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see ⁵⁵ Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ⁵⁵ Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see ⁵⁵ Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ⁵⁵ Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see ⁵⁵ Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ⁵⁵ Co	1E+3	7E+2	3E-7	1E-9	-	-
27	Cobalt-60m ²	W, see ⁵⁵ Co	1E+6	4E+6	2E-3	6E-6	-	-
		St wall	(1E+6)	-	-	-	2E-2	2E-1
		Y, see ⁵⁵ Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see ⁵⁵ Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ⁵⁵ Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-61 ²	W, see ⁵⁵ Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ⁵⁵ Co	2E+4	6E+4	2E-5	8E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio-nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
27	Cobalt-62m ²	W, see ⁵⁵ Co	4E+4	2E+5	7E-5	2E-7	-	-
		St wall	(5E+4)	-	-	-	7E-4	7E-3
		Y, see ⁵⁵ Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
	W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-	-
	Vapor	-	1E+3	5E-7	2E-9	-	-	-
28	Nickel-57	D, see ⁵⁶ Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
	W, see ⁵⁶ Ni	-	3E+3	1E-6	4E-9	-	-	-
	Vapor	-	6E+3	3E-6	9E-9	-	-	-
28	Nickel-59	D, see ⁵⁶ Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
	W, see ⁵⁶ Ni	-	7E+3	3E-6	1E-8	-	-	-
	Vapor	-	2E+3	8E-7	3E-9	-	-	-
28	Nickel-63	D, see ⁵⁶ Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
	W, see ⁵⁶ Ni	-	3E+3	1E-6	4E-9	-	-	-
	Vapor	-	8E+2	3E-7	1E-9	-	-	-
28	Nickel-65	D, see ⁵⁶ Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
	W, see ⁵⁶ Ni	-	3E+4	1E-5	4E-8	-	-	-
	Vapor	-	2E+4	7E-6	2E-8	-	-	-
28	Nickel-66	D, see ⁵⁶ Ni	4E+2	2E+3	7E-7	2E-9	-	-
	LLI wall	(5E+2)	-	-	-	6E-6	6E-5	6E-5
	W, see ⁵⁶ Ni	-	6E+2	3E-7	9E-10	-	-	-
	Vapor	-	3E+3	1E-6	4E-9	-	-	-
29	Copper-60 ²	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
	St wall	(3E+4)	-	-	-	4E-4	4E-3	4E-3
	W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-	-
	Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-	-
29	Copper-61	D, see ⁶⁰ Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ⁶⁰ Cu	-	4E+4	2E-5	6E-8	-	-	-
	Y, see ⁶⁰ Cu	-	4E+4	1E-5	5E-8	-	-	-
29	Copper-64	D, see ⁶⁰ Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ⁶⁰ Cu	-	2E+4	1E-5	3E-8	-	-	-
	Y, see ⁶⁰ Cu	-	2E+4	9E-6	3E-8	-	-	-
29	Copper-67	D, see ⁶⁰ Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
	W, see ⁶⁰ Cu	-	5E+3	2E-6	7E-9	-	-	-
	Y, see ⁶⁰ Cu	-	5E+3	2E-6	6E-9	-	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63 ²	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
		St wall	(3E+4)	-	-	-	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69 ²	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65 ²	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
		St wall	(6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see ⁶⁵ Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ⁶⁵ Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see ⁶⁵ Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ⁶⁵ Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68 ²	D, see ⁶⁵ Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ⁶⁵ Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70 ²	D, see ⁶⁵ Ga	5E+4	2E+5	7E-5	2E-7	-	-
		St wall	(7E+4)	-	-	-	1E-3	1E-2
		W, see ⁶⁵ Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see ⁶⁵ Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ⁶⁵ Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see ⁶⁵ Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ⁶⁵ Ga	-	2E+4	6E-6	2E-8	-	-
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32	Germanium-67 ²	D, see ⁶⁶ Ge	3E+4	9E+4	4E-5	1E-7	-	-
		St wall	(4E+4)	-	-	-	6E-4	6E-3
		W, see ⁶⁶ Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see ⁶⁶ Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ⁶⁶ Ge	-	1E+2	4E-8	1E-10	-	-
32	Germanium-69	D, see ⁶⁶ Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ⁶⁶ Ge	-	8E+3	3E-6	1E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)	
32	Germanium-71	D, see ⁶⁶ Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see ⁶⁶ Ge	-	4E+4	2E-5	6E-8	-	-
32	Germanium-75 ²	D, see ⁶⁶ Ge	4E+4	8E+4	3E-5	1E-7	-	-
		St wall						
		(7E+4)	-	-	-	9E-4		9E-3
		W, see ⁶⁶ Ge	-	8E+4	4E-5	1E-7	-	-
32	Germanium-77	D, see ⁶⁶ Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ⁶⁶ Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78 ²	D, see ⁶⁶ Ge	2E+4	2E+4	9E-6	3E-8	-	-
		St wall						
		(2E+4)	-	-	-	3E-4		3E-3
		W, see ⁶⁶ Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69 ²	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
		St wall						
		(4E+4)	-	-	-	6E-4		6E-3
33	Arsenic-70 ²	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
		LLI wall						
		(5E+3)	-	-	-	6E-5		6E-4
33	Arsenic-78 ²	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70 ²	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-
34	Selenium-73m ²	D, see ⁷⁰ Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see ⁷⁰ Se	3E+4	1E+5	6E-5	2E-7	-	-
34	Selenium-73	D, see ⁷⁰ Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see ⁷⁰ Se	-	2E+4	7E-6	2E-8	-	-
34	Selenium-75	D, see ⁷⁰ Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see ⁷⁰ Se	-	6E+2	3E-7	8E-10	-	-
34	Selenium-79	D, see ⁷⁰ Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see ⁷⁰ Se	-	6E+2	2E-7	8E-10	-	-
34	Selenium-81m ²	D, see ⁷⁰ Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see ⁷⁰ Se	2E+4	7E+4	3E-5	1E-7	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
		Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio- nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
34	Selenium-81 ²	D, see ⁷⁰ Se	6E+4	2E+5	9E-5	3E-7	-	-
		St wall	(8E+4)	-	-	1E-3	1E-2	
		W, see ⁷⁰ Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83 ²	D, see ⁷⁰ Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ⁷⁰ Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m ²	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
		St wall	(2E+4)	-	-	3E-4	3E-3	
		W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-
35	Bromine-74 ²	D, see ^{74m} Br	2E+4	7E+4	3E-5	1E-7	-	-
		St wall	(4E+4)	-	-	5E-4	5E-3	
		W, see ^{74m} Br	-	8E+4	4E-5	1E-7	-	-
35	Bromine-75 ²	D, see ^{74m} Br	3E+4	5E+4	2E-5	7E-8	-	-
		St wall	(4E+4)	-	-	5E-4	5E-3	
		W, see ^{74m} Br	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see ^{74m} Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m} Br	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see ^{74m} Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m} Br	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see ^{74m} Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m} Br	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80 ²	D, see ^{74m} Br	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(9E+4)	-	-	1E-3	1E-2	
		W, see ^{74m} Br	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see ^{74m} Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m} Br	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see ^{74m} Br	5E+4	6E+4	3E-5	9E-8	-	-
		St wall	(7E+4)	-	-	9E-4	9E-3	
		W, see ^{74m} Br	-	6E+4	3E-5	9E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
		Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
35	Bromine-84 ²	D, see ^{74m} Br	2E+4	6E+4	2E-5	8E-8	-	-
		St wall						
		(3E+4)	-	-	-	4E-4	4E-3	
	W, see ^{74m} Br	-	6E+4	3E-5	9E-8	-	-	
36	Krypton-74 ²	Submersion ¹	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion ¹	-	-	9E-6	4E-8	-	-
36	Krypton-77 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
36	Krypton-79	Submersion ¹	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion ¹	-	-	7E-4	3E-6	-	-
36	Krypton-83m ²	Submersion ¹	-	-	1E-2	5E-5	-	-
36	Krypton-85m	Submersion ¹	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion ¹	-	-	1E-4	7E-7	-	-
36	Krypton-87 ²	Submersion ¹	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion ¹	-	-	2E-6	9E-9	-	-
37	Rubidium-79 ²	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
		St wall						
		(6E+4)	-	-	-	8E-4	8E-3	
37	Rubidium-81m ²	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
		St wall						
		(3E+5)	-	-	-	4E-3	4E-2	
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88 ²	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
		St wall						
		(3E+4)	-	-	-	4E-4	4E-3	
37	Rubidium-89 ²	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-
		St wall						
		(6E+4)	-	-	-	9E-4	9E-3	
38	Strontium-80 ²	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	Y, all insoluble compounds and SrTiO	-	1E+4	5E-6	2E-8	-	-	
38	Strontium-81 ²	D, see ⁸⁰ Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
	Y, see ⁸⁰ Sr	2E+4	8E+4	3E-5	1E-7	-	-	
38	Strontium-82	D, see ⁸⁰ Sr	3E+2	4E+2	2E-7	6E-10	-	-
		LLI wall						
		(2E+2)	-	-	-	3E-6	3E-5	
	Y, see ⁸⁰ Sr	2E+2	9E+1	4E-8	1E-10	-	-	

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
38	Strontium-83	D, see ⁸⁰ Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ⁸⁰ Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m ²	D, see ⁸⁰ Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ⁸⁰ Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see ⁸⁰ Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ⁸⁰ Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see ⁸⁰ Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ⁸⁰ Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see ⁸⁰ Sr	6E+2	8E+2	4E-7	1E-9	-	-
		LLI wall	(6E+2)	-	-	-	8E-6	8E-5
		Y, see ⁸⁰ Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see ⁸⁰ Sr	3E+1	2E+1	8E-9	-	-	-
		Bone surf	(4E+1)	(2E+1)	-	3E-11	5E-7	5E-6
		Y, see ⁸⁰ Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see ⁸⁰ Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ⁸⁰ Sr	-	4E+3	1E-6	5E-9	-	-
38	Strontium-92	D, see ⁸⁰ Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ⁸⁰ Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m ²	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see ^{86m} Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m} Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see ^{86m} Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m} Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see ^{86m} Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m} Y	-	2E+2	1E-7	3E-10	-	-
39	Yttrium-90m	W, see ^{86m} Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m} Y	-	1E+4	5E-6	2E-8	-	-
39	Yttrium-90	W, see ^{86m} Y	4E+2	7E+2	3E-7	9E-10	-	-
		LLI wall	(5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{86m} Y	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m ²	W, see ^{86m} Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m} Y	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see ^{86m} Y	5E+2	2E+2	7E-8	2E-10	-	-
		LLI wall	(6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{86m} Y	-	1E+2	5E-8	2E-10	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
39	Yttrium-92	W, see ^{86m} Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{86m} Y	-	8E+3	3E-6	1E-8	-	-
39	Yttrium-93	W, see ^{86m} Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{86m} Y	-	2E+3	1E-6	3E-9	-	-
39	Yttrium-94 ²	W, see ^{86m} Y	2E+4 St wall	8E+4	3E-5	1E-7	-	-
			(3E+4)	-	-	-	4E-4	4E-3
		Y, see ^{86m} Y	-	8E+4	3E-5	1E-7	-	-
39	Yttrium-95 ²	W, see ^{86m} Y	4E+4 St wall	2E+5	6E-5	2E-7	-	-
			(5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{86m} Y	-	1E+5	6E-5	2E-7	-	-
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
		Y, carbide	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-88	D, see ⁸⁶ Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see ⁸⁶ Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see ⁸⁶ Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see ⁸⁶ Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ⁸⁶ Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see ⁸⁶ Zr	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-93	D, see ⁸⁶ Zr	1E+3 Bone surf	6E+0 Bone surf	3E-9	-	-	-
			(3E+3)	(2E+1)	-	2E-11	4E-5	4E-4
		W, see ⁸⁶ Zr	-	2E+1 Bone surf	1E-8	-	-	-
			-	(6E+1)	-	9E-11	-	-
		Y, see ⁸⁶ Zr	-	6E+1 Bone surf	2E-8	-	-	-
			-	(7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see ⁸⁶ Zr	1E+3	1E+2 Bone surf	5E-8	-	2E-5	2E-4
			-	(3E+2)	-	4E-10	-	-
		W, see ⁸⁶ Zr	-	4E+2	2E-7	5E-10	-	-
		Y, see ⁸⁶ Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-97	D, see ⁸⁶ Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see ⁸⁶ Zr	-	1E+3	6E-7	2E-9	-	-
		Y, see ⁸⁶ Zr	-	1E+3	5E-7	2E-9	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio-nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)
41	Niobium-88 ²	W, all compounds except those given for Y	5E+4 St wall (7E+4)	2E+5 -	9E-5 -	3E-7 -	- 1E-3 1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-
41	Niobium-89 ²	W, see ⁸⁸ Nb	1E+4	4E+4	2E-5	6E-8	1E-4
	(66 min)	Y, see ⁸⁸ Nb	-	4E+4	2E-5	5E-8	-
41	Niobium-89	W, see ⁸⁸ Nb	5E+3	2E+4	8E-6	3E-8	7E-5
	(122 min)	Y, see ⁸⁸ Nb	-	2E+4	6E-6	2E-8	-
41	Niobium-90	W, see ⁸⁸ Nb	1E+3	3E+3	1E-6	4E-9	1E-5
		Y, see ⁸⁸ Nb	-	2E+3	1E-6	3E-9	-
41	Niobium-93m	W, see ⁸⁸ Nb	9E+3 LLI wall (1E+4)	2E+3 -	8E-7 -	3E-9 -	- 2E-4 2E-3
		Y, see ⁸⁸ Nb	-	2E+2	7E-8	2E-10	-
41	Niobium-94	W, see ⁸⁸ Nb	9E+2	2E+2	8E-8	3E-10	1E-5
		Y, see ⁸⁸ Nb	-	2E+1	6E-9	2E-11	-
41	Niobium-95m	W, see ⁸⁸ Nb	2E+3 LLI wall (2E+3)	3E+3 -	1E-6 -	4E-9 -	- 3E-5 3E-4
		Y, see ⁸⁸ Nb	-	2E+3	9E-7	3E-9	-
41	Niobium-95	W, see ⁸⁸ Nb	2E+3	1E+3	5E-7	2E-9	3E-5
		Y, see ⁸⁸ Nb	-	1E+3	5E-7	2E-9	-
41	Niobium-96	W, see ⁸⁸ Nb	1E+3	3E+3	1E-6	4E-9	2E-5
		Y, see ⁸⁸ Nb	-	2E+3	1E-6	3E-9	-
41	Niobium-97 ²	W, see ⁸⁸ Nb	2E+4	8E+4	3E-5	1E-7	3E-4
		Y, see ⁸⁸ Nb	-	7E+4	3E-5	1E-7	-
41	Niobium-98 ²	W, see ⁸⁸ Nb	1E+4	5E+4	2E-5	8E-8	2E-4
		Y, see ⁸⁸ Nb	-	5E+4	2E-5	7E-8	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5
		Y, oxides, hydroxides, and MoS	2E+3	5E+3	2E-6	6E-9	-
42	Molybdenum-93m	D, see ⁹⁰ Mo	9E+3	2E+4	7E-6	2E-8	6E-5
		Y, see ⁹⁰ Mo	4E+3	1E+4	6E-6	2E-8	-
42	Molybdenum-93	D, see ⁹⁰ Mo	4E+3	5E+3	2E-6	8E-9	5E-5
		Y, see ⁹⁰ Mo	2E+4	2E+2	8E-8	2E-10	-
42	Molybdenum-99	D, see ⁹⁰ Mo	2E+3 LLI wall (1E+3)	3E+3 -	1E-6 -	4E-9 -	- 2E-5 2E-4
		Y, see ⁹⁰ Mo	1E+3	1E+3	6E-7	2E-9	-

		Table I Occupational Values				Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio-nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)	
42	Molybdenum-101 ²	D, see ⁹⁰ Mo	4E+4 St wall (5E+4)	1E+5	6E-5	2E-7	-	-
		Y, see ⁹⁰ Mo	-	1E+5	6E-5	2E-7	7E-4	7E-3
43	Technetium-93m ²	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see ^{93m} Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m} Tc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m ²	D, see ^{93m} Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m} Tc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see ^{93m} Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m} Tc	-	2E+4	1E-5	3E-8	-	-
43	Technetium-95m	D, see ^{93m} Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m} Tc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see ^{93m} Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m} Tc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m ²	D, see ^{93m} Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m} Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see ^{93m} Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m} Tc	-	2E+3	9E-7	3E-9	-	-
43	Technetium-97m	D, see ^{93m} Tc	5E+3 St wall (7E+3)	7E+3	3E-6	-	6E-5	6E-4
		W, see ^{93m} Tc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see ^{93m} Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m} Tc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see ^{93m} Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m} Tc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see ^{93m} Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m} Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see ^{93m} Tc	4E+3 St wall (6E+3)	5E+3	2E-6	-	6E-5	6E-4
		W, see ^{93m} Tc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101 ²	D, see ^{93m} Tc	9E+4 St wall (1E+5)	3E+5	1E-4	5E-7	-	-
		W, see ^{93m} Tc	-	4E+5	2E-4	5E-7	2E-3	2E-2

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
43	Technetium-104 ²	D, see ^{93m} Tc	2E+4	7E+4	3E-5	1E-7	-	-
		St wall						
		(3E+4)	-	-	-	4E-4	4E-3	
		W, see ^{93m} Tc	-	9E+4	4E-5	1E-7	-	-
44	Ruthenium-94 ²	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	-	6E+4	3E-5	9E-8	-	-
		Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-
44	Ruthenium-97	D, see ⁹⁴ Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ⁹⁴ Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see ⁹⁴ Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see ⁹⁴ Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ⁹⁴ Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see ⁹⁴ Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see ⁹⁴ Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ⁹⁴ Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see ⁹⁴ Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see ⁹⁴ Ru	2E+2	9E+1	4E-8	1E-10	-	-
		LLI wall						
		(2E+2)	-	-	-	3E-6	3E-5	
		W, see ⁹⁴ Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see ⁹⁴ Ru	-	1E+1	5E-9	2E-11	-	-
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	-	8E+4	3E-5	1E-7	-	-
		Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45	Rhodium-99	D, see ^{99m} Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{99m} Rh	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{99m} Rh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see ^{99m} Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m} Rh	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{99m} Rh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see ^{99m} Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m} Rh	-	8E+3	4E-6	1E-8	-	-
		Y, see ^{99m} Rh	-	8E+3	3E-6	1E-8	-	-
45	Rhodium-101	D, see ^{99m} Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m} Rh	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{99m} Rh	-	2E+2	6E-8	2E-10	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)
45	Rhodium-102m	D, see ^{99m} Rh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		W, see ^{99m} Rh	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{99m} Rh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see ^{99m} Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m} Rh	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{99m} Rh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m ²	D, see ^{99m} Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m} Rh	-	1E+6	5E-4	2E-6	-	-
		Y, see ^{99m} Rh	-	1E+6	5E-4	2E-6	-	-
45	Rhodium-105	D, see ^{99m} Rh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{99m} Rh	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{99m} Rh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see ^{99m} Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m} Rh	-	4E+4	2E-5	5E-8	-	-
		Y, see ^{99m} Rh	-	4E+4	1E-5	5E-8	-	-
45	Rhodium-107 ²	D, see ^{99m} Rh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{99m} Rh	-	3E+5	1E-4	4E-7	-	-
		Y, see ^{99m} Rh	-	3E+5	1E-4	3E-7	-	-
46	Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see ¹⁰⁰ Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ¹⁰⁰ Pd	-	3E+4	1E-5	5E-8	-	-
		Y, see ¹⁰⁰ Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see ¹⁰⁰ Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall (7E+3)	-	-	-	1E-4	1E-3
		W, see ¹⁰⁰ Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see ¹⁰⁰ Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see ¹⁰⁰ Pd	3E+4 LLI wall	2E+4 Kidneys	9E-6	-	-	-
			(4E+4)	(2E+4)	-	3E-8	5E-4	5E-3
		W, see ¹⁰⁰ Pd	-	7E+3	3E-6	1E-8	-	-
		Y, see ¹⁰⁰ Pd	-	4E+2	2E-7	6E-10	-	-

			Table I			Table II		Table III
			Occupational Values			Effluent Concentrations		Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
46	Palladium-109	D, see ¹⁰⁰ Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see ¹⁰⁰ Pd	-	5E+3	2E-6	8E-9	-	-
		Y, see ¹⁰⁰ Pd	-	5E+3	2E-6	6E-9	-	-
47	Silver-102 ²	D, all compounds except those given for W and Y	5E+4	2E+5	8E-5	2E-7	-	-
			(6E+4)	-	-	-	9E-4	9E-3
		W, nitrates and sulfides	-	2E+5	9E-5	3E-7	-	-
		Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
		D, see ¹⁰² Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
47	Silver-103 ²	W, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
		D, see ¹⁰² Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
47	Silver-104m ²	W, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
		Y, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
		D, see ¹⁰² Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
47	Silver-104 ²	W, see ¹⁰² Ag	-	1E+5	6E-5	2E-7	-	-
		Y, see ¹⁰² Ag	-	1E+5	6E-5	2E-7	-	-
		D, see ¹⁰² Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
47	Silver-105	W, see ¹⁰² Ag	-	2E+3	7E-7	2E-9	-	-
		Y, see ¹⁰² Ag	-	2E+3	7E-7	2E-9	-	-
		D, see ¹⁰² Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
47	Silver-106m	W, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-
		D, see ¹⁰² Ag	6E+4	2E+5	8E-5	3E-7	-	-
47	Silver-106 ²		(6E+4)	-	-	-	9E-4	9E-3
		W, see ¹⁰² Ag	-	2E+5	9E-5	3E-7	-	-
		Y, see ¹⁰² Ag	-	2E+5	8E-5	3E-7	-	-
		D, see ¹⁰² Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
47	Silver-108m	W, see ¹⁰² Ag	-	3E+2	1E-7	4E-10	-	-
		Y, see ¹⁰² Ag	-	2E+1	1E-8	3E-11	-	-
		D, see ¹⁰² Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
47	Silver-110m	W, see ¹⁰² Ag	-	2E+2	8E-8	3E-10	-	-
		Y, see ¹⁰² Ag	-	9E+1	4E-8	1E-10	-	-
		D, see ¹⁰² Ag	9E+2	2E+3	6E-7	-	-	-
47	Silver-111		(1E+3)	(2E+3)	-	2E-9	2E-5	2E-4
		W, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio-nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)
47 Silver-112	D, see ¹⁰² Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ¹⁰² Ag	-	1E+4	4E-6	1E-8	-	-
	Y, see ¹⁰² Ag	-	9E+3	4E-6	1E-8	-	-
47 Silver-115 ²	D, see ¹⁰² Ag	3E+4 St wall	9E+4	4E-5	1E-7	-	-
		(3E+4)	-	-	-	4E-4	4E-3
	W, see ¹⁰² Ag	-	9E+4	4E-5	1E-7	-	-
	Y, see ¹⁰² Ag	-	8E+4	3E-5	1E-7	-	-
48 Cadmium-104 ²	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
	Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48 Cadmium-107	D, see ¹⁰⁴ Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
	W, see ¹⁰⁴ Cd	-	6E+4	2E-5	8E-8	-	-
	Y, see ¹⁰⁴ Cd	-	5E+4	2E-5	7E-8	-	-
48 Cadmium-109	D, see ¹⁰⁴ Cd	3E+2	4E+1	1E-8	-	-	-
		Kidneys	Kidneys				
		(4E+2)	(5E+1)	-	7E-11	6E-6	6E-5
	W, see ¹⁰⁴ Cd	-	1E+2 Kidneys	5E-8	-	-	-
		-	(1E+2)	-	2E-10	-	-
	Y, see ¹⁰⁴ Cd	-	1E+2	5E-8	2E-10	-	-
48 Cadmium-113m	D, see ¹⁰⁴ Cd	2E+1	2E+0	1E-9	-	-	-
		Kidneys	Kidneys				
		(4E+1)	(4E+0)	-	5E-12	5E-7	5E-6
	W, see ¹⁰⁴ Cd	-	8E+0 Kidneys	4E-9	-	-	-
		-	(1E+1)	-	2E-11	-	-
	Y, see ¹⁰⁴ Cd	-	1E+1	5E-9	2E-11	-	-
48 Cadmium-113	D, see ¹⁰⁴ Cd	2E+1	2E+0	9E-10	-	-	-
		Kidneys	Kidneys				
		(3E+1)	(3E+0)	-	5E-12	4E-7	4E-6
	W, see ¹⁰⁴ Cd	-	8E+0 Kidneys	3E-9	-	-	-
		-	(1E+1)	-	2E-11	-	-
	Y, see ¹⁰⁴ Cd	-	1E+1	6E-9	2E-11	-	-
48 Cadmium-115m	D, see ¹⁰⁴ Cd	3E+2	5E+1 Kidneys	2E-8	-	4E-6	4E-5
		-	(8E+1)	-	1E-10	-	-
	W, see ¹⁰⁴ Cd	-	1E+2	5E-8	2E-10	-	-
	Y, see ¹⁰⁴ Cd	-	1E+2	6E-8	2E-10	-	-

			Table I			Table II		Table III
			Occupational Values			Effluent Concentrations		Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
48	Cadmium-115	D, see ¹⁰⁴ Cd	9E+2 LLI wall	1E+3	6E-7	2E-9	-	-
			(1E+3)	-	-	-	1E-5	1E-4
		W, see ¹⁰⁴ Cd	-	1E+3	5E-7	2E-9	-	-
		Y, see ¹⁰⁴ Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see ¹⁰⁴ Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ¹⁰⁴ Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ¹⁰⁴ Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see ¹⁰⁴ Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ¹⁰⁴ Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ¹⁰⁴ Cd	-	1E+4	6E-6	2E-8	-	-
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49	Indium-110 ²	D, see ¹⁰⁹ In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
(69.1 min)		W, see ¹⁰⁹ In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110	D, see ¹⁰⁹ In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
(4.9 h)		W, see ¹⁰⁹ In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see ¹⁰⁹ In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see ¹⁰⁹ In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112 ²	D, see ¹⁰⁹ In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see ¹⁰⁹ In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m ²	D, see ¹⁰⁹ In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see ¹⁰⁹ In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see ¹⁰⁹ In	3E+2 LLI wall	6E+1	3E-8	9E-11	-	-
			(4E+2)	-	-	-	5E-6	5E-5
		W, see ¹⁰⁹ In	-	1E+2	4E-8	1E-10	-	-
49	Indium-115m	D, see ¹⁰⁹ In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ¹⁰⁹ In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see ¹⁰⁹ In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see ¹⁰⁹ In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m ²	D, see ¹⁰⁹ In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see ¹⁰⁹ In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m ²	D, see ¹⁰⁹ In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ¹⁰⁹ In	-	4E+4	2E-5	6E-8	-	-
49	Indium-117 ²	D, see ¹⁰⁹ In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ¹⁰⁹ In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m ²	D, see ¹⁰⁹ In	4E+4 St wall	1E+5	5E-5	2E-7	-	-
			(5E+4)	-	-	-	7E-4	7E-3
		W, see ¹⁰⁹ In	-	1E+5	6E-5	2E-7	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
50 Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
	W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-
50 Tin-111 ²	D, see ¹¹⁰ Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
	W, see ¹¹⁰ Sn	-	3E+5	1E-4	4E-7	-	-
50 Tin-113	D, see ¹¹⁰ Sn	2E+3 LLI wall	1E+3	5E-7	2E-9	-	-
		(2E+3)	-	-	-	3E-5	3E-4
	W, see ¹¹⁰ Sn	-	5E+2	2E-7	8E-10	-	-
50 Tin-117m	D, see ¹¹⁰ Sn	2E+3 LLI wall	1E+3 Bone surf	5E-7	-	-	-
		(2E+3)	(2E+3)	-	3E-9	3E-5	3E-4
	W, see ¹¹⁰ Sn	-	1E+3	6E-7	2E-9	-	-
50 Tin-119m	D, see ¹¹⁰ Sn	3E+3 LLI wall	2E+3	1E-6	3E-9	-	-
		(4E+3)	-	-	-	6E-5	6E-4
	W, see ¹¹⁰ Sn	-	1E+3	4E-7	1E-9	-	-
50 Tin-121m	D, see ¹¹⁰ Sn	3E+3 LLI wall	9E+2	4E-7	1E-9	-	-
		(4E+3)	-	-	-	5E-5	5E-4
	W, see ¹¹⁰ Sn	-	5E+2	2E-7	8E-10	-	-
50 Tin-121	D, see ¹¹⁰ Sn	6E+3 LLI wall	2E+4	6E-6	2E-8	-	-
		(6E+3)	-	-	-	8E-5	8E-4
	W, see ¹¹⁰ Sn	-	1E+4	5E-6	2E-8	-	-
50 Tin-123m ²	D, see ¹¹⁰ Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
	W, see ¹¹⁰ Sn	-	1E+5	6E-5	2E-7	-	-
50 Tin-123	D, see ¹¹⁰ Sn	5E+2 LLI wall	6E+2	3E-7	9E-10	-	-
		(6E+2)	-	-	-	9E-6	9E-5
	W, see ¹¹⁰ Sn	-	2E+2	7E-8	2E-10	-	-
50 Tin-125	D, see ¹¹⁰ Sn	4E+2 LLI wall	9E+2	4E-7	1E-9	-	-
		(5E+2)	-	-	-	6E-6	6E-5
	W, see ¹¹⁰ Sn	-	4E+2	1E-7	5E-10	-	-
50 Tin-126	D, see ¹¹⁰ Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
	W, see ¹¹⁰ Sn	-	7E+1	3E-8	9E-11	-	-
50 Tin-127	D, see ¹¹⁰ Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	W, see ¹¹⁰ Sn	-	2E+4	8E-6	3E-8	-	-
50 Tin-128 ²	D, see ¹¹⁰ Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, see ¹¹⁰ Sn	-	4E+4	1E-5	5E-8	-	-

			Table I			Table II		Table III
			Occupational Values			Effluent Concentrations		Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
			Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
51	Antimony-115 ²	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m ²	D, see ¹¹⁵ Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ¹¹⁵ Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-116 ²	D, see ¹¹⁵ Sb	7E+4	3E+5	1E-4	4E-7	-	-
		St wall	(9E+4)	-	-	-	1E-3	1E-2
		W, see ¹¹⁵ Sb	-	3E+5	1E-4	5E-7	-	-
51	Antimony-117	D, see ¹¹⁵ Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ¹¹⁵ Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see ¹¹⁵ Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ¹¹⁵ Sb	5E+3	2E+4	9E-6	3E-8	-	-
51	Antimony-119	D, see ¹¹⁵ Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ¹¹⁵ Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120 ² (16 min)	D, see ¹¹⁵ Sb	1E+5	4E+5	2E-4	6E-7	-	-
		St wall	(2E+5)	-	-	-	2E-3	2E-2
		W, see ¹¹⁵ Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5.76 d)	D, see ¹¹⁵ Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ¹¹⁵ Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	Antimony-122	D, see ¹¹⁵ Sb	8E+2	2E+3	1E-6	3E-9	-	-
		LLI wall	(8E+2)	-	-	-	1E-5	1E-4
		W, see ¹¹⁵ Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m ²	D, see ¹¹⁵ Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ¹¹⁵ Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see ¹¹⁵ Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ¹¹⁵ Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see ¹¹⁵ Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see ¹¹⁵ Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m ²	D, see ¹¹⁵ Sb	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(7E+4)	-	-	-	9E-4	9E-3
		W, see ¹¹⁵ Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see ¹¹⁵ Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ¹¹⁵ Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see ¹¹⁵ Sb	8E+2	2E+3	9E-7	3E-9	-	-
		LLI wall	(8E+2)	-	-	-	1E-5	1E-4
		W, see ¹¹⁵ Sb	7E+2	9E+2	4E-7	1E-9	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
51	Antimony-128 ² (10.4 min)	D, see ¹¹⁵ Sb	8E+4	4E+5	2E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ¹¹⁵ Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128 (9.01 h)	D, see ¹¹⁵ Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ¹¹⁵ Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see ¹¹⁵ Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ¹¹⁵ Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130 ²	D, see ¹¹⁵ Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ¹¹⁵ Sb	-	8E+4	3E-5	1E-7	-	-
51	Antimony-131 ²	D, see ¹¹⁵ Sb	1E+4 Thyroid	2E+4 Thyroid	1E-5	-	-	-
			(2E+4)	(4E+4)	-	6E-8	2E-4	2E-3
		W, see ¹¹⁵ Sb	-	2E+4 Thyroid	1E-5	-	-	-
			-	(4E+4)	-	6E-8	-	-
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52	Tellurium-121m	D, see ¹¹⁶ Te	5E+2 Bone surf	2E+2 Bone surf	8E-8	-	-	-
			(7E+2)	(4E+2)	-	5E-10	1E-5	1E-4
		W, see ¹¹⁶ Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see ¹¹⁶ Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ¹¹⁶ Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see ¹¹⁶ Te	6E+2 Bone surf	2E+2 Bone surf	9E-8	-	-	-
			(1E+3)	(5E+2)	-	8E-10	1E-5	1E-4
		W, see ¹¹⁶ Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see ¹¹⁶ Te	5E+2 Bone surf	2E+2 Bone surf	8E-8	-	-	-
			(1E+3)	(5E+2)	-	7E-10	2E-5	2E-4
		W, see ¹¹⁶ Te	-	4E+2 Bone surf	2E-7	-	-	-
			-	(1E+3)	-	2E-9	-	-
52	Tellurium-125m	D, see ¹¹⁶ Te	1E+3 Bone surf	4E+2 Bone surf	2E-7	-	-	-
			(1E+3)	(1E+3)	-	1E-9	2E-5	2E-4
		W, see ¹¹⁶ Te	-	7E+2	3E-7	1E-9	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
52	Tellurium-127m	D, see ¹¹⁶ Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
				Bone surf				
			-	(4E+2)	-	6E-10	-	-
		W, see ¹¹⁶ Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see ¹¹⁶ Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ¹¹⁶ Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see ¹¹⁶ Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ¹¹⁶ Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129 ²	D, see ¹¹⁶ Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ¹¹⁶ Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see ¹¹⁶ Te	3E+2	4E+2	2E-7	-	-	-
			Thyroid	Thyroid				
			(6E+2)	(1E+3)	-	2E-9	8E-6	8E-5
		W, see ¹¹⁶ Te	-	4E+2	2E-7	-	-	-
				Thyroid				
			-	(9E+2)	-	1E-9	-	-
52	Tellurium-131 ²	D, see ¹¹⁶ Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid	Thyroid				
			(6E+3)	(1E+4)	-	2E-8	8E-5	8E-4
		W, see ¹¹⁶ Te	-	5E+3	2E-6	-	-	-
				Thyroid				
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see ¹¹⁶ Te	2E+2	2E+2	9E-8	-	-	-
			Thyroid	Thyroid				
			(7E+2)	(8E+2)	-	1E-9	9E-6	9E-5
		W, see ¹¹⁶ Te	-	2E+2	9E-8	-	-	-
				Thyroid				
			-	(6E+2)	-	9E-10	-	-
52	Tellurium-133m ²	D, see ¹¹⁶ Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid	Thyroid				
			(6E+3)	(1E+4)	-	2E-8	9E-5	9E-4
		W, see ¹¹⁶ Te	-	5E+3	2E-6	-	-	-
				Thyroid				
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-133 ²	D, see ¹¹⁶ Te	1E+4	2E+4	9E-6	-	-	-
			Thyroid	Thyroid				
			(3E+4)	(6E+4)	-	8E-8	4E-4	4E-3
		W, see ¹¹⁶ Te	-	2E+4	9E-6	-	-	-
				Thyroid				
			-	(6E+4)	-	8E-8	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio-nuclide No.	Class		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
52 Tellurium-134 ²	D, see ¹¹⁶ Te		2E+4	2E+4	1E-5	-	-	-
		Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3	
	W, see ¹¹⁶ Te	-	2E+4 Thyroid	1E-5	-	-	-	
		-	(5E+4)	-	7E-8	-	-	
53 Iodine-120m ²	D, all compounds		1E+4	2E+4	9E-6	3E-8	-	-
		Thyroid (1E+4)	-	-	-	2E-4	2E-3	
53 Iodine-120 ²	D, all compounds		4E+3	9E+3	4E-6	-	-	-
		Thyroid (8E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3	
53 Iodine-121	D, all compounds		1E+4	2E+4	8E-6	-	-	-
		Thyroid (3E+4)	Thyroid (5E+4)	-	7E-8	4E-4	4E-3	
53 Iodine-123	D, all compounds		3E+3	6E+3	3E-6	-	-	-
		Thyroid (1E+4)	Thyroid (2E+4)	-	2E-8	1E-4	1E-3	
53 Iodine-124	D, all compounds		5E+1	8E+1	3E-8	-	-	-
		Thyroid (2E+2)	Thyroid (3E+2)	-	4E-10	2E-6	2E-5	
53 Iodine-125	D, all compounds		4E+1	6E+1	3E-8	-	-	-
		Thyroid (1E+2)	Thyroid (2E+2)	-	3E-10	2E-6	2E-5	
53 Iodine-126	D, all compounds		2E+1	4E+1	1E-8	-	-	-
		Thyroid (7E+1)	Thyroid (1E+2)	-	2E-10	1E-6	1E-5	
53 Iodine-128 ²	D, all compounds		4E+4	1E+5	5E-5	2E-7	-	-
		St wall (6E+4)	-	-	-	8E-4	8E-3	
53 Iodine-129	D, all compounds		5E+0	9E+0	4E-9	-	-	-
		Thyroid (2E+1)	Thyroid (3E+1)	-	4E-11	2E-7	2E-6	
53 Iodine-130	D, all compounds		4E+2	7E+2	3E-7	-	-	-
		Thyroid (1E+3)	Thyroid (2E+3)	-	3E-9	2E-5	2E-4	
53 Iodine-131	D, all compounds		3E+1	5E+1	2E-8	-	-	-
		Thyroid (9E+1)	Thyroid (2E+2)	-	2E-10	1E-6	1E-5	
53 Iodine-132m ²	D, all compounds		4E+3	8E+3	4E-6	-	-	-
		Thyroid (1E+4)	Thyroid (2E+4)	-	3E-8	1E-4	1E-3	

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
53	Iodine-132	D, all compounds	4E+3	8E+3	3E-6	-	-	-
			Thyroid (9E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-133	D, all compounds	1E+2	3E+2	1E-7	-	-	-
			Thyroid (5E+2)	Thyroid (9E+2)	-	1E-9	7E-6	7E-5
53	Iodine-134 ²	D, all compounds	2E+4	5E+4	2E-5	6E-8	-	-
			Thyroid (3E+4)	-	-	-	4E-4	4E-3
53	Iodine-135	D, all compounds	8E+2	2E+3	7E-7	-	-	-
			Thyroid (3E+3)	Thyroid (4E+3)	-	6E-9	3E-5	3E-4
54	Xenon-120 ²	Submersion ¹	-	-	1E-5	4E-8	-	-
54	Xenon-121 ²	Submersion ¹	-	-	2E-6	1E-8	-	-
54	Xenon-122	Submersion ¹	-	-	7E-5	3E-7	-	-
54	Xenon-123	Submersion ¹	-	-	6E-6	3E-8	-	-
54	Xenon-125	Submersion ¹	-	-	2E-5	7E-8	-	-
54	Xenon-127	Submersion ¹	-	-	1E-5	6E-8	-	-
54	Xenon-129m	Submersion ¹	-	-	2E-4	9E-7	-	-
54	Xenon-131m	Submersion ¹	-	-	4E-4	2E-6	-	-
54	Xenon-133m	Submersion ¹	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion ¹	-	-	1E-4	5E-7	-	-
54	Xenon-135m ²	Submersion ¹	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion ¹	-	-	1E-5	7E-8	-	-
54	Xenon-138 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
55	Cesium-125 ²	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130 ²	D, all compounds	6E+4	2E+5	8E-5	3E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m ²	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
55 Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55 Cesium-138 ²	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
		St wall (3E+4)	-	-	-	4E-4	4E-3
56 Barium-126 ²	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56 Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56 Barium-131m ²	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
		St wall (5E+5)	-	-	-	7E-3	7E-2
56 Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56 Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
56 Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56 Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56 Barium-139 ²	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56 Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
56 Barium-141 ²	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56 Barium-142 ²	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57 Lanthanum-131 ²	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
	W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57 Lanthanum-132	D, see ¹³¹ La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
	W, see ¹³¹ La	-	1E+4	5E-6	2E-8	-	-
57 Lanthanum-135	D, see ¹³¹ La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
	W, see ¹³¹ La	-	9E+4	4E-5	1E-7	-	-
57 Lanthanum-137	D, see ¹³¹ La	1E+4	6E+1	3E-8	-	2E-4	2E-3
		Liver -	(7E+1)	-	1E-10	-	-
	W, see ¹³¹ La	-	3E+2	1E-7	-	-	-
		Liver -	(3E+2)	-	4E-10	-	-
57 Lanthanum-138	D, see ¹³¹ La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
	W, see ¹³¹ La	-	1E+1	6E-9	2E-11	-	-
57 Lanthanum-140	D, see ¹³¹ La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
	W, see ¹³¹ La	-	1E+3	5E-7	2E-9	-	-
57 Lanthanum-141	D, see ¹³¹ La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
	W, see ¹³¹ La	-	1E+4	5E-6	2E-8	-	-
57 Lanthanum-142 ²	D, see ¹³¹ La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
	W, see ¹³¹ La	-	3E+4	1E-5	5E-8	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
57	Lanthanum-143 ²	D, see ¹³¹ La	4E+4 St wall (4E+4)	1E+5 - 9E+4	4E-5 - 4E-5	1E-7 - 1E-7	- 5E-4 -	- 5E-3 -
58	Cerium-134	W, see ¹³¹ La	-	9E+4	4E-5	1E-7	-	-
		W, all compounds except those given for Y	5E+2 LLI wall (6E+2)	7E+2 - -	3E-7 - -	1E-9 - -	- 8E-6 -	- 8E-5 -
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see ¹³⁴ Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ¹³⁴ Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see ¹³⁴ Ce	2E+3 LLI wall (2E+3)	4E+3 - -	2E-6 - -	6E-9 - -	- 3E-5 -	- 3E-4 -
58	Cerium-137	Y, see ¹³⁴ Ce	-	4E+3	2E-6	5E-9	-	-
		W, see ¹³⁴ Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ¹³⁴ Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see ¹³⁴ Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ¹³⁴ Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see ¹³⁴ Ce	2E+3 LLI wall (2E+3)	7E+2 - -	3E-7 - -	1E-9 - -	- 3E-5 -	- 3E-4 -
		Y, see ¹³⁴ Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see ¹³⁴ Ce	1E+3 LLI wall (1E+3)	2E+3 - -	8E-7 - -	3E-9 - -	- 2E-5 -	- 2E-4 -
		Y, see ¹³⁴ Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see ¹³⁴ Ce	2E+2 LLI wall (3E+2)	3E+1 - -	1E-8 - -	4E-11 - -	- 3E-6 -	- 3E-5 -
		Y, see ¹³⁴ Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium- 136 ²	W, all compounds except those given for Y	5E+4 St wall (7E+4)	2E+5 - -	1E-4 - -	3E-7 - -	- 1E-3 -	- 1E-2 -
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59	Praseodymium- 137 ²	W, see ¹³⁶ Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ¹³⁶ Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium- 138m	W, see ¹³⁶ Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ¹³⁶ Pr	-	4E+4	2E-5	6E-8	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
59	Praseodymium-139	W, see ¹³⁶ Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ¹³⁶ Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-142m ²	W, see ¹³⁶ Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see ¹³⁶ Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-142	W, see ¹³⁶ Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see ¹³⁶ Pr	-	2E+3	8E-7	3E-9	-	-
59	Praseodymium-143	W, see ¹³⁶ Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall					
			(1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹³⁶ Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144 ²	W, see ¹³⁶ Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall					
			(4E+4)	-	-	-	6E-4	6E-3
		Y, see ¹³⁶ Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see ¹³⁶ Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ¹³⁶ Pr	-	8E+3	3E-6	1E-8	-	-
59	Praseodymium-147 ²	W, see ¹³⁶ Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall					
			(8E+4)	-	-	-	1E-3	1E-2
		Y, see ¹³⁶ Pr	-	2E+5	8E-5	3E-7	-	-
60	Neodymium-136 ²	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see ¹³⁶ Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see ¹³⁶ Nd	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-139m	W, see ¹³⁶ Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see ¹³⁶ Nd	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-139 ²	W, see ¹³⁶ Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see ¹³⁶ Nd	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-141	W, see ¹³⁶ Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ¹³⁶ Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see ¹³⁶ Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall					
			(1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹³⁶ Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149 ²	W, see ¹³⁶ Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see ¹³⁶ Nd	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151 ²	W, see ¹³⁶ Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see ¹³⁶ Nd	-	2E+5	8E-5	3E-7	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
		Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
61	Promethium-141 ²	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(6E+4)	-	-	8E-4	8E-3	
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61	Promethium-143	W, see ¹⁴¹ Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ¹⁴¹ Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see ¹⁴¹ Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see ¹⁴¹ Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
		Bone surf	-	(2E+2)	-	3E-10	-	-
		Y, see ¹⁴¹ Pm	-	2E+2	8E-8	3E-10	-	-
61	Promethium-146	W, see ¹⁴¹ Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see ¹⁴¹ Pm	4E+3	1E+2	5E-8	-	-	-
		Bone surf	(5E+3)	(2E+2)	-	3E-10	7E-5	7E-4
		Y, see ¹⁴¹ Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see ¹⁴¹ Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see ¹⁴¹ Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see ¹⁴¹ Pm	4E+2	5E+2	2E-7	8E-10	-	-
		LLI wall	(5E+2)	-	-	7E-6	7E-5	
		Y, see ¹⁴¹ Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see ¹⁴¹ Pm	1E+3	2E+3	8E-7	3E-9	-	-
		LLI wall	(1E+3)	-	-	2E-5	2E-4	
		Y, see ¹⁴¹ Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see ¹⁴¹ Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ¹⁴¹ Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see ¹⁴¹ Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m ²	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141 ²	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
		St wall	(6E+4)	-	-	8E-4	8E-3	
62	Samarium-142 ²	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E-2	1E-11	-	-	-
		Bone surf		Bone surf				

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
		(3E+1)	(6E-2)	-	9E-14	3E-7	3E-6	
62	Samarium-147	W, all compounds	2E+1 Bone surf	4E-2 Bone surf	2E-11	-	-	-
		(3E+1)	(7E-2)	-	1E-13	4E-7	4E-6	
62	Samarium-151	W, all compounds	1E+4 LLI wall	1E+2 Bone surf	4E-8	-	-	-
		(1E+4)	(2E+2)	-	2E-10	2E-4	2E-3	
62	Samarium-153	W, all compounds	2E+3 LLI wall	3E+3	1E-6	4E-9	-	-
		(2E+3)	-	-	-	3E-5	3E-4	
62	Samarium-155 ²	W, all compounds	6E+4 St wall	2E+5	9E-5	3E-7	-	-
		(8E+4)	-	-	-	1E-3	1E-2	
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1 Bone surf	4E-8	-	5E-5	5E-4
		-	(1E+2)	-	2E-10	-	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158 ²	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145 ²	D, all compounds except those given for W	5E+4 St wall	2E+5	6E-5	2E-7	-	-
		(5E+4)	-	-	-	6E-4	6E-3	6E-3
	W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-	-
64	Gadolinium-146	D, see ¹⁴⁵ Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
	W, see ¹⁴⁵ Gd	-	3E+2	1E-7	4E-10	-	-	-
64	Gadolinium-147	D, see ¹⁴⁵ Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
	W, see ¹⁴⁵ Gd	-	4E+3	1E-6	5E-9	-	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
			Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio-nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
64	Gadolinium-148	D, see ¹⁴⁵ Gd	1E+1	8E+3	3E-12	-	-	-	
			Bone surf	Bone surf					
	(2E+1)	(2E+2)	-	2E-14	3E-7	3E-6			
	W, see ¹⁴⁵ Gd	-	3E-2	1E-11	-	-	-		
		Bone surf							
-		(6E-2)	-	8E-14	-	-			
64	Gadolinium-149	D, see ¹⁴⁵ Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4	
		W, see ¹⁴⁵ Gd	-	2E+3	1E-6	3E-9	-	-	
64	Gadolinium-151	D, see ¹⁴⁵ Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4	
			Bone surf						
	-	(6E+2)	-	9E-10	-	-			
	W, see ¹⁴⁵ Gd	-	1E+3	5E-7	2E-9	-	-		
64		Gadolinium-152	D, see ¹⁴⁵ Gd	2E+1	1E-2	4E-12	-	-	-
	Bone surf			Bone surf					
	(3E+1)	(2E-2)	-	3E-14	4E-7	4E-6			
	W, see ¹⁴⁵ Gd	-	4E-2	2E-11	-	-	-		
		Bone surf							
-		(8E-2)	-	1E-13	-	-			
64	Gadolinium-153	D, see ¹⁴⁵ Gd	5E+3	1E+2	6E-8	-	6E-5	6E-4	
			Bone surf						
	-	(2E+2)	-	3E-10	-	-			
	W, see ¹⁴⁵ Gd	-	6E+2	2E-7	8E-10	-	-		
64		Gadolinium-159	D, see ¹⁴⁵ Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ¹⁴⁵ Gd		-	6E+3	2E-6	8E-9	-	-	
65	Terbium-147 ²	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3	
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4	
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4	
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4	
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4	
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4	
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4	
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3	
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3	
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4	
65	Terbium-157	W, all compounds	5E+4	3E+2	1E-7	-	-	-	
			LLI wall	Bone surf					
			(5E+4)	(6E+2)	-	8E-10	7E-4	7E-3	

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
		Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3 LLI wall	2E+3	7E-7	2E-9	-	-
		(2E+3)	-	-	-	3E-5		3E-4
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2 LLI wall	7E+2	3E-7	1E-9	-	-
		(8E+2)	-	-	-	1E-5		1E-4
67	Holmium-155 ²	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157 ²	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159 ²	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m ²	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162 ²	W, all compounds	5E+5 St wall	2E+6	1E-3	3E-6	-	-
		(8E+5)	-	-	-	1E-2		1E-1
67	Holmium-164m ²	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164 ²	W, all compounds	2E+5 St wall	6E+5	3E-4	9E-7	-	-
		(2E+5)	-	-	-	3E-3		3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2 LLI wall	2E+3	7E-7	2E-9	-	-
		(9E+2)	-	-	-	1E-5		1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3 LLI wall	3E+3	1E-6	4E-9	-	-
		(4E+3)	-	-	-	5E-5		5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3 LLI wall	1E+3	6E-7	2E-9	-	-
		(E+3)	-	-	-	2E-5		2E-4
69	Thulium-162 ²	W, all compounds	7E+4 St wall	3E+5	1E-4	4E-7	-	-
		(7E+4)	-	-	-	1E-3		1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3 LLI wall	2E+3	8E-7	3E-9	-	-
		(2E+3)	-	-	-	3E-5		3E-4

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
		LLI wall	(1E+3)	-	-	-	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
		LLI wall	(1E+4)	Bone surf	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
		LLI wall	(8E+2)	-	-	-	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175 ²	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
		St wall	(9E+4)	-	-	-	1E-3	1E-2
70	Ytterbium-162 ²	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
	Y, oxides, hydroxides, and fluorides		-	3E+5	1E-4	4E-7	-	-
70	Ytterbium-166	W, see ¹⁶² Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
	Y, see ¹⁶² Yb		-	2E+3	8E-7	3E-9	-	-
70	Ytterbium-167 ²	W, see ¹⁶² Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
	Y, see ¹⁶² Yb		-	7E+5	3E-4	1E-6	-	-
70	Ytterbium-169	W, see ¹⁶² Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
	Y, see ¹⁶² Yb		-	7E+2	3E-7	1E-9	-	-
70	Ytterbium-175	W, see ¹⁶² Yb	3E+3	4E+3	1E-6	5E-9	-	-
		LLI wall	(3E+3)	-	-	-	4E-5	4E-4
	Y, see ¹⁶² Yb		-	3E+3	1E-6	5E-9	-	-
70	Ytterbium-177 ²	W, see ¹⁶² Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
	Y, see ¹⁶² Yb		-	5E+4	2E-5	6E-8	-	-
70	Ytterbium-178 ²	W, see ¹⁶² Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	Y, see ¹⁶² Yb		-	4E+4	2E-5	5E-8	-	-
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
	Y, oxides, hydroxides, and fluorides		-	4E+3	2E-6	6E-9	-	-
71	Lutetium-170	W, see ¹⁶⁹ Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
	Y, see ¹⁶⁹ Lu		-	2E+3	8E-7	3E-9	-	-
71	Lutetium-171	W, see ¹⁶⁹ Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
	Y, see ¹⁶⁹ Lu		-	2E+3	8E-7	3E-9	-	-
71	Lutetium-172	W, see ¹⁶⁹ Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
	Y, see ¹⁶⁹ Lu		-	1E+3	5E-7	2E-9	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)
71	Lutetium-173	W, see ¹⁶⁹ Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
				Bone surf				
			-	(5E+2)	-	6E-10	-	-
		Y, see ¹⁶⁹ Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see ¹⁶⁹ Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall	Bone surf				
			(3E+3)	(3E+2)	-	5E-10	4E-5	4E-4
		Y, see ¹⁶⁹ Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see ¹⁶⁹ Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
				Bone surf				
			-	(2E+2)	-	3E-10	-	-
		Y, see ¹⁶⁹ Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see ¹⁶⁹ Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ¹⁶⁹ Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see ¹⁶⁹ Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
				Bone surf				
			-	(1E+1)	-	2E-11	-	-
		Y, see ¹⁶⁹ Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see ¹⁶⁹ Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
				Bone surf				
			-	(1E+2)	-	2E-10	-	-
		Y, see ¹⁶⁹ Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see ¹⁶⁹ Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall					
			(3E+3)	-	-	-	4E-5	4E-4
		Y, see ¹⁶⁹ Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m ²	W, see ¹⁶⁹ Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St wall					
			(6E+4)	-	-	-	8E-4	8E-3
		Y, see ¹⁶⁹ Lu	-	2E+5	7E-5	2E-7	-	-
71	Lutetium-178 ²	W, see ¹⁶⁹ Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall					
			(4E+4)	-	-	-	6E-4	6E-3
		Y, see ¹⁶⁹ Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see ¹⁶⁹ Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ¹⁶⁹ Lu	-	2E+4	6E-6	3E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
		Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72	Hafnium-172	D, see ¹⁷⁰ Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
				Bone surf				
			-	(2E+1)	-	3E-11	-	-
		W, see ¹⁷⁰ Hf	-	4E+1	2E-8	-	-	-
				Bone surf				
			-	(6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see ¹⁷⁰ Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ¹⁷⁰ Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see ¹⁷⁰ Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
				Bone surf				
			-	(1E+3)	-	1E-9	-	-
		W, see ¹⁷⁰ Hf	-	1E+3	5E-7	2E-9	-	-
72	Hafnium-177m ²	D, see ¹⁷⁰ Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ¹⁷⁰ Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see ¹⁷⁰ Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
				Bone surf				
			-	(2E+0)	-	3E-12	-	-
		W, see ¹⁷⁰ Hf	-	5E+0	2E-9	-	-	-
				Bone surf				
			-	(9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see ¹⁷⁰ Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
				Bone surf				
			-	(6E+2)	-	8E-10	-	-
		W, see ¹⁷⁰ Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see ¹⁷⁰ Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ¹⁷⁰ Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see ¹⁷⁰ Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
				Bone surf				
			-	(4E+2)	-	6E-10	-	-
		W, see ¹⁷⁰ Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m ²	D, see ¹⁷⁰ Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ¹⁷⁰ Hf	-	1E+5	6E-5	2E-7	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
72	Hafnium-182	D, see ¹⁷⁰ Hf	2E+2	8E-1	3E-10	-	-	-
			Bone surf	Bone surf				
			(4E+2)	(2E+0)	-	2E-12	5E-6	5E-5
		W, see ¹⁷⁰ Hf	-	3E+0	1E-9	-	-	-
				Bone surf				
			-	(7E+0)	-	1E-11	-	-
72	Hafnium-183 ²	D, see ¹⁷⁰ Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ¹⁷⁰ Hf	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-172 ²	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73	Tantalum-173	W, see ¹⁷² Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ¹⁷² Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174 ²	W, see ¹⁷² Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ¹⁷² Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see ¹⁷² Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ¹⁷² Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see ¹⁷² Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ¹⁷² Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see ¹⁷² Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ¹⁷² Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see ¹⁷² Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see ¹⁷² Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see ¹⁷² Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ¹⁷² Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see ¹⁷² Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ¹⁷² Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see ¹⁷² Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ¹⁷² Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m ²	W, see ¹⁷² Ta	2E+5	5E+5	2E-4	8E-7	-	-
		St wall	(2E+5)	-	-	-	3E-3	3E-2
		Y, see ¹⁷² Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see ¹⁷² Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ¹⁷² Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see ¹⁷² Ta	9E+2	1E+3	5E-7	2E-9	-	-
		LLI wall	(1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹⁷² Ta	-	1E+3	4E-7	1E-9	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
73	Tantalum-184	W, see ¹⁷² Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see ¹⁷² Ta	-	5E+3	2E-6	7E-9	-	-
73	Tantalum-185 ²	W, see ¹⁷² Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see ¹⁷² Ta	-	6E+4	3E-5	9E-8	-	-
73	Tantalum-186 ²	W, see ¹⁷² Ta	5E+4	2E+5	1E-4	3E-7	-	-
		St wall	(7E+4)	-	-	-	1E-3	1E-2
		Y, see ¹⁷² Ta	-	2E+5	9E-5	3E-7	-	-
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74	Tungsten-179 ²	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-
		LLI wall	(3E+3)	-	-	-	4E-5	4E-4
74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
		LLI wall	(5E+2)	-	-	-	7E-6	7E-5
75	Rhenium-177 ²	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
		St wall	(1E+5)	-	-	-	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75	Rhenium-178 ²	D, see ¹⁷⁷ Re	7E+4	3E+5	1E-4	4E-7	-	-
		St wall	(1E+5)	-	-	-	1E-3	1E-2
		W, see ¹⁷⁷ Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see ¹⁷⁷ Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ¹⁷⁷ Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182	D, see ¹⁷⁷ Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
	(12.7 h)	W, see ¹⁷⁷ Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182	D, see ¹⁷⁷ Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	(64.0 h)	W, see ¹⁷⁷ Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see ¹⁷⁷ Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ¹⁷⁷ Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see ¹⁷⁷ Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ¹⁷⁷ Re	-	1E+3	6E-7	2E-9	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio-nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
75	Rhenium-186m	D, see ¹⁷⁷ Re	1E+3	2E+3	7E-7	-	-
		St wall	(2E+3)	(2E+3)	-	3E-9	2E-5
							2E-4
		W, see ¹⁷⁷ Re	-	2E+2	6E-8	2E-10	-
75	Rhenium-186	D, see ¹⁷⁷ Re	2E+3	3E+3	1E-6	4E-9	3E-5
		W, see ¹⁷⁷ Re	-	2E+3	7E-7	2E-9	-
75	Rhenium-187	D, see ¹⁷⁷ Re	6E+5	8E+5	4E-4	-	8E-3
		St wall	(9E+5)	-	1E-6	-	-
		W, see ¹⁷⁷ Re	-	1E+5	4E-5	1E-7	-
75	Rhenium-188m ²	D, see ¹⁷⁷ Re	8E+4	1E+5	6E-5	2E-7	1E-3
		W, see ¹⁷⁷ Re	-	1E+5	6E-5	2E-7	-
75	Rhenium-188	D, see ¹⁷⁷ Re	2E+3	3E+3	1E-6	4E-9	2E-5
		W, see ¹⁷⁷ Re	-	3E+3	1E-6	4E-9	-
75	Rhenium-189	D, see ¹⁷⁷ Re	3E+3	5E+3	2E-6	7E-9	4E-5
		W, see ¹⁷⁷ Re	-	4E+3	2E-6	6E-9	-
76	Osmium-180 ²	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-
76	Osmium-181 ²	D, see ¹⁸⁰ Os	1E+4	4E+4	2E-5	6E-8	2E-4
		W, see ¹⁸⁰ Os	-	5E+4	2E-5	6E-8	-
		Y, see ¹⁸⁰ Os	-	4E+4	2E-5	6E-8	-
76	Osmium-182	D, see ¹⁸⁰ Os	2E+3	6E+3	2E-6	8E-9	3E-5
		W, see ¹⁸⁰ Os	-	4E+3	2E-6	6E-9	-
		Y, see ¹⁸⁰ Os	-	4E+3	2E-6	6E-9	-
76	Osmium-185	D, see ¹⁸⁰ Os	2E+3	5E+2	2E-7	7E-10	3E-5
		W, see ¹⁸⁰ Os	-	8E+2	3E-7	1E-9	-
		Y, see ¹⁸⁰ Os	-	8E+2	3E-7	1E-9	-
76	Osmium-189m	D, see ¹⁸⁰ Os	8E+4	2E+5	1E-4	3E-7	1E-3
		W, see ¹⁸⁰ Os	-	2E+5	9E-5	3E-7	-
		Y, see ¹⁸⁰ Os	-	2E+5	7E-5	2E-7	-
76	Osmium-191m	D, see ¹⁸⁰ Os	1E+4	3E+4	1E-5	4E-8	2E-4
		W, see ¹⁸⁰ Os	-	2E+4	8E-6	3E-8	-
		Y, see ¹⁸⁰ Os	-	2E+4	7E-6	2E-8	-
76	Osmium-191	D, see ¹⁸⁰ Os	2E+3	2E+3	9E-7	3E-9	-
		LLI wall	(3E+3)	-	-	-	3E-5
							3E-4
		W, see ¹⁸⁰ Os	-	2E+3	7E-7	2E-9	-
		Y, see ¹⁸⁰ Os	-	1E+3	6E-7	2E-9	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
76 Osmium-193	D, see ¹⁸⁰ Os	2E+3	5E+3	2E-6	6E-9	-	-
		LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see ¹⁸⁰ Os	-	3E+3	1E-6	4E-9	-
	Y, see ¹⁸⁰ Os	-	3E+3	1E-6	4E-9	-	-
	76 Osmium-194	D, see ¹⁸⁰ Os	4E+2	4E+1	2E-8	6E-11	-
LLI wall (6E+2)			-	-	-	8E-6	8E-5
W, see ¹⁸⁰ Os			-	6E+1	2E-8	8E-11	-
Y, see ¹⁸⁰ Os		-	8E+0	3E-9	1E-11	-	-
77 Iridium-182 ²		D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-
	St wall (4E+4)		-	-	-	6E-4	6E-3
	W, halides, nitrates, and metallic iridium		-	2E+5	6E-5	2E-7	-
	Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
	77 Iridium-184	D, see ¹⁸² Ir	8E+3	2E+4	1E-5	3E-8	1E-4
W, see ¹⁸² Ir		-	3E+4	1E-5	5E-8	-	-
Y, see ¹⁸² Ir		-	3E+4	1E-5	4E-8	-	-
77 Iridium-185	D, see ¹⁸² Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see ¹⁸² Ir	-	1E+4	5E-6	2E-8	-	-
	Y, see ¹⁸² Ir	-	1E+4	4E-6	1E-8	-	-
77 Iridium-186	D, see ¹⁸² Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	W, see ¹⁸² Ir	-	6E+3	3E-6	9E-9	-	-
	Y, see ¹⁸² Ir	-	6E+3	2E-6	8E-9	-	-
77 Iridium-187	D, see ¹⁸² Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
	W, see ¹⁸² Ir	-	3E+4	1E-5	4E-8	-	-
	Y, see ¹⁸² Ir	-	3E+4	1E-5	4E-8	-	-
77 Iridium-188	D, see ¹⁸² Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
	W, see ¹⁸² Ir	-	4E+3	1E-6	5E-9	-	-
	Y, see ¹⁸² Ir	-	3E+3	1E-6	5E-9	-	-
77 Iridium-189	D, see ¹⁸² Ir	5E+3	5E+3	2E-6	7E-9	-	-
		LLI wall (5E+3)	-	-	-	7E-5	7E-4
	W, see ¹⁸² Ir	-	4E+3	2E-6	5E-9	-	-
	Y, see ¹⁸² Ir	-	4E+3	1E-6	5E-9	-	-
	77 Iridium-190m ²	D, see ¹⁸² Ir	2E+5	2E+5	8E-5	3E-7	2E-3
W, see ¹⁸² Ir		-	2E+5	9E-5	3E-7	-	-
Y, see ¹⁸² Ir		-	2E+5	8E-5	3E-7	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
77 Iridium-190	D, see ¹⁸² Ir		1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
	W, see ¹⁸² Ir		-	1E+3	4E-7	1E-9	-	-
	Y, see ¹⁸² Ir		-	9E+2	4E-7	1E-9	-	-
77 Iridium-192m	D, see ¹⁸² Ir		3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
	W, see ¹⁸² Ir		-	2E+2	9E-8	3E-10	-	-
	Y, see ¹⁸² Ir		-	2E+1	6E-9	2E-11	-	-
77 Iridium-192	D, see ¹⁸² Ir		9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
	W, see ¹⁸² Ir		-	4E+2	2E-7	6E-10	-	-
	Y, see ¹⁸² Ir		-	2E+2	9E-8	3E-10	-	-
77 Iridium-194m	D, see ¹⁸² Ir		6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
	W, see ¹⁸² Ir		-	2E+2	7E-8	2E-10	-	-
	Y, see ¹⁸² Ir		-	1E+2	4E-8	1E-10	-	-
77 Iridium-194	D, see ¹⁸² Ir		1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	W, see ¹⁸² Ir		-	2E+3	9E-7	3E-9	-	-
	Y, see ¹⁸² Ir		-	2E+3	8E-7	3E-9	-	-
77 Iridium-195m	D, see ¹⁸² Ir		8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
	W, see ¹⁸² Ir		-	3E+4	1E-5	4E-8	-	-
	Y, see ¹⁸² Ir		-	2E+4	9E-6	3E-8	-	-
77 Iridium-195	D, see ¹⁸² Ir		1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ¹⁸² Ir		-	5E+4	2E-5	7E-8	-	-
	Y, see ¹⁸² Ir		-	4E+4	2E-5	6E-8	-	-
78 Platinum-186	D, all compounds		1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78 Platinum-188	D, all compounds		2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78 Platinum-189	D, all compounds		1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78 Platinum-191	D, all compounds		4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78 Platinum-193m	D, all compounds		3E+3	6E+3	3E-6	8E-9	-	-
			LLI wall					
			(3E+4)	-	-	-	4E-5	4E-4
78 Platinum-193	D, all compounds		4E+4	2E+4	1E-5	3E-8	-	-
			LLI wall					
			(5E+4)	-	-	-	6E-4	6E-3
78 Platinum-195m	D, all compounds		2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall					
			(2E+3)	-	-	-	3E-5	3E-4
78 Platinum-197m ²	D, all compounds		2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78 Platinum-197	D, all compounds		3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78 Platinum-199 ²	D, all compounds		5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78 Platinum-200	D, all compounds		1E+3	3E+3	1E-6	5E-9	2E-5	2E-4

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
		Oral Ingestion	INHALATION				Monthly Average	
Atomic Radio- nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)	
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see ¹⁹³ Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ¹⁹³ Au	-	5E+3	2E-6	8E-9	-	-
		Y, see ¹⁹³ Au	-	5E+3	2E-6	7E-9	-	-
79	Gold-195	D, see ¹⁹³ Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ¹⁹³ Au	-	1E+3	6E-7	2E-9	-	-
		Y, see ¹⁹³ Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see ¹⁹³ Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ¹⁹³ Au	-	1E+3	5E-7	2E-9	-	-
		Y, see ¹⁹³ Au	-	1E+3	5E-7	2E-9	-	-
79	Gold-198	D, see ¹⁹³ Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ¹⁹³ Au	-	2E+3	8E-7	3E-9	-	-
		Y, see ¹⁹³ Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see ¹⁹³ Au	3E+3 LLI wall	9E+3	4E-6	1E-8	-	-
			(3E+3)	-	-	-	4E-5	4E-4
		W, see ¹⁹³ Au	-	4E+3	2E-6	6E-9	-	-
		Y, see ¹⁹³ Au	-	4E+3	2E-6	5E-9	-	-
79	Gold-200m	D, see ¹⁹³ Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ¹⁹³ Au	-	3E+3	1E-6	4E-9	-	-
		Y, see ¹⁹³ Au	-	2E+4	1E-6	3E-9	-	-
79	Gold-200 ²	D, see ¹⁹³ Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ¹⁹³ Au	-	8E+4	3E-5	1E-7	-	-
		Y, see ¹⁹³ Au	-	7E+4	3E-5	1E-7	-	-
79	Gold-201 ²	D, see ¹⁹³ Au	7E+4 St wall	2E+5	9E-5	3E-7	-	-
			(9E+4)	-	-	-	1E-3	1E-2
		W, see ¹⁹³ Au	-	2E+5	1E-4	3E-7	-	-
		Y, see ¹⁹³ Au	-	2E+5	9E-5	3E-7	-	-
80	Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80	Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see ^{193m} Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{193m} Hg	-	4E+4	2E-5	6E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
80 Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
	Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
	D, see ^{193m} Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
	W, see ^{193m} Hg	-	1E+2	5E-8	2E-10	-	-
80 Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
	Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
	D, see ^{193m} Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
	W, see ^{193m} Hg	-	4E+3	2E-6	5E-9	-	-
80 Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
	D, see ^{193m} Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
	W, see ^{193m} Hg	-	3E+4	1E-5	5E-8	-	-
80 Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
	Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
	D, see ^{193m} Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{193m} Hg	-	5E+3	2E-6	7E-9	-	-
80 Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
	Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
	D, see ^{193m} Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
	W, see ^{193m} Hg	-	9E+3	4E-6	1E-8	-	-
80 Mercury-199m ²	Vapor	-	8E+4	3E-5	1E-7	-	-
	Organic D	6E+4 St wall	2E+5	7E-5	2E-7	-	-
		(1E+5)	-	-	-	1E-3	1E-2
	D, see ^{193m} Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
80 Mercury-203	W, see ^{193m} Hg	-	2E+5	7E-5	2E-7	-	-
	Vapor	-	8E+2	4E-7	1E-9	-	-
	Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
	D, see ^{193m} Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
81 Thallium-194m ²	W, see ^{193m} Hg	-	1E+3	5E-7	2E-9	-	-
	D, all compounds	5E+4 St wall	2E+5	6E-5	2E-7	-	-
81 Thallium-194 ²		(7E+4)	-	-	-	1E-3	1E-2
	D, all compounds	3E+5 St wall	6E+5	2E-4	8E-7	-	-
		(3E+5)	-	-	-	4E-3	4E-2
81 Thallium-195 ²	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81 Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81 Thallium-198m ²	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81 Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81 Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81 Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81 Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81 Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4

		Table I			Table II		Table III
		Occupational Values			Effluent Concentrations		Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
81 Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82 Lead-195m ²	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82 Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82 Lead-199 ²	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82 Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82 Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82 Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82 Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82 Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82 Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82 Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82 Lead-210	D, all compounds	6E-1 Bone surf	2E-1 Bone surf	1E-10	-	-	-
		(1E+0)	(4E-1)	-	6E-13	1E-8	1E-7
82 Lead-211 ²	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82 Lead-212	D, all compounds	8E+1 Bone surf	3E+1	1E-8	5E-11	-	-
		(1E+2)	-	-	-	2E-6	2E-5
82 Lead-214 ²	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83 Bismuth-200 ²	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
	W, all other compounds	-	1E+5	4E-5	1E-7	-	-
83 Bismuth-201 ²	D, see ²⁰⁰ Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see ²⁰⁰ Bi	-	4E+4	2E-5	5E-8	-	-
83 Bismuth-202 ²	D, see ²⁰⁰ Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ²⁰⁰ Bi	-	8E+4	3E-5	1E-7	-	-
83 Bismuth-203	D, see ²⁰⁰ Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
	W, see ²⁰⁰ Bi	-	6E+3	3E-6	9E-9	-	-
83 Bismuth-205	D, see ²⁰⁰ Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
	W, see ²⁰⁰ Bi	-	1E+3	5E-7	2E-9	-	-
83 Bismuth-206	D, see ²⁰⁰ Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
	W, see ²⁰⁰ Bi	-	9E+2	4E-7	1E-9	-	-
83 Bismuth-207	D, see ²⁰⁰ Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
	W, see ²⁰⁰ Bi	-	4E+2	1E-7	5E-10	-	-
83 Bismuth-210m	D, see ²⁰⁰ Bi	4E+1	5E+0	2E-9	-	-	-
	Kidneys	Kidneys					
		(6E+1)	(6E+0)	-	9E-12	8E-7	8E-6
	W, see ²⁰⁰ Bi	-	7E-1	3E-10	9E-13	-	-
83 Bismuth-210	D, see ²⁰⁰ Bi	8E+2	2E+2	1E-7	-	1E-5	1E-4
	Kidneys						
		-	(4E+2)	-	5E-10	-	-
	W, see ²⁰⁰ Bi	-	3E+1	1E-8	4E-11	-	-

			Table I			Table II		Table III
			Occupational Values			Effluent Concentrations		Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
83	Bismuth-212 ²	D, see ²⁰⁰ Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see ²⁰⁰ Bi	-	3E+2	1E-7	4E-10	-	-
83	Bismuth-213 ²	D, see ²⁰⁰ Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see ²⁰⁰ Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-214 ²	D, see ²⁰⁰ Bi	2E+4	8E+2	3E-7	1E-9	-	-
		St wall						
		(2E+4)	-	-	-	-	3E-4	3E-3
		W, see ²⁰⁰ Bi	-	9E-2	4E-7	1E-9	-	-
84	Polonium-203 ²	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84	Polonium-205 ²	D, see ²⁰³ Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ²⁰³ Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see ²⁰³ Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ²⁰³ Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see ²⁰³ Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ²⁰³ Po	-	6E-1	3E-10	9E-13	-	-
85	Astatine-207 ²	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	-	2E+3	9E-7	3E-9	-	-
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	-	5E+1	2E-8	8E-11	-	-
86	Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
		With daughters present	-	2E+1	9E-9	3E-11	-	-
				(or 12 working level months)	(or 1.0 working level)			
86	Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
		With daughters present	-	1E+2	3E-8	1E-10	-	-
				(or 4 working level months)	(or 0.33 working level)			
87	Francium-222 ²	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223 ²	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	7E-1	3E-10	9E-13	-	-
		Bone surf						
		(9E+0)	-	-	-	-	1E-7	1E-6

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.	Class		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
88 Radium-224	W, all compounds		8E+0	2E+0	7E-10	2E-12	-	-
		Bone surf						
		(2E+1)	-	-	-	-	2E-7	2E-6
88 Radium-225	W, all compounds		8E+0	7E-1	3E-10	9E-13	-	-
		Bone surf						
		(2E+1)	-	-	-	-	2E-7	2E-6
88 Radium-226	W, all compounds		2E+0	6E-1	3E-10	9E-13	-	-
		Bone surf						
		(5E+0)	-	-	-	-	6E-8	6E-7
88 Radium-227 ²	W, all compounds		2E+4	1E+4	6E-6	-	-	-
		Bone surf		Bone surf				
		(2E+4)	(2E+4)	-	-	3E-8	3E-4	3E-3
88 Radium-228	W, all compounds		2E+0	1E+0	5E-10	2E-12	-	-
		Bone surf						
		(4E+0)	-	-	-	-	6E-8	6E-7
89 Actinium-224	D, all compounds except those given for W and Y		2E+3 LLI wall	3E+1 Bone surf	1E-8	-	-	-
		(2E+3)	(4E+1)	-	-	5E-11	3E-5	3E-4
	W, halides and nitrates		-	5E+1	2E-8	7E-11	-	-
	Y, oxides and hydroxides		-	5E+1	2E-8	6E-11	-	-
89 Actinium-225	D, see ²²⁴ Ac		5E+1 LLI wall	3E-1 Bone surf	1E-10	-	-	-
		(5E+1)	(5E-1)	-	-	7E-13	7E-7	7E-6
	W, see ²²⁴ Ac		-	6E-1	3E-10	9E-13	-	-
	Y, see ²²⁴ Ac		-	6E-1	3E-10	9E-13	-	-
89 Actinium-226	D, see ²²⁴ Ac		1E+2 LLI wall	3E+0 Bone surf	1E-9	-	-	-
		(1E+2)	(4E+0)	-	-	5E-12	2E-6	2E-5
	W, see ²²⁴ Ac		-	5E+0	2E-9	7E-12	-	-
	Y, see ²²⁴ Ac		-	5E+0	2E-9	6E-12	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
89	Actinium-227	D, see ²²⁴ Ac	2E-1 Bone surf	4E-4 Bone surf	2E-13	-	-	-
			(4E-1)	(8E-4)	-	1E-15	5E-9	5E-8
			-	2E-3 Bone surf	7E-13	-	-	-
		W, see ²²⁴ Ac	-	(3E-3)	-	4E-15	-	-
			-	4E-3	2E-12	6E-15	-	-
89	Actinium-228	D, see ²²⁴ Ac	2E+3	9E+0 Bone surf	4E-9	-	3E-5	3E-4
			-	(2E+1)	-	2E-11	-	-
			-	4E+1 Bone surf	2E-8	-	-	-
		W, see ²²⁴ Ac	-	(6E+1)	-	8E-11	-	-
			-	4E+1	2E-8	6E-11	-	-
90	Thorium-226 ²	W, all compounds except those given for Y	5E+3 St wall	2E+2	6E-8	2E-10	-	-
			(5E+3)	-	-	-	7E-5	7E-4
			-	1E+2	6E-8	2E-10	-	-
		Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
			-	1E+2	3E-1	1E-10	5E-13	2E-6
90	Thorium-227	W, see ²²⁶ Th	-	3E-1	1E-10	5E-13	-	-
			-	3E-1	1E-10	5E-13	-	-
			-	3E-1	1E-10	5E-13	-	-
		Y, see ²²⁶ Th	6E+0 Bone surf	1E-2 Bone surf	4E-12	-	-	-
			(1E+1)	(2E-2)	-	3E-14	2E-7	2E-6
90	Thorium-228	W, see ²²⁶ Th	-	2E-2	7E-12	2E-14	-	-
			-	2E-2	7E-12	2E-14	-	-
			-	2E-2	7E-12	2E-14	-	-
		Y, see ²²⁶ Th	6E-1 Bone surf	9E-4 Bone surf	4E-13	-	-	-
			(1E+0)	(2E-3)	-	3E-15	2E-8	2E-7
90	Thorium-229	W, see ²²⁶ Th	-	2E-3 Bone surf	1E-12	-	-	-
			-	2E-3 Bone surf	1E-12	-	-	-
			-	2E-3 Bone surf	1E-12	-	-	-
		Y, see ²²⁶ Th	-	(3E-3)	-	4E-15	-	-
			-	(3E-3)	-	4E-15	-	-
90	Thorium-230	W, see ²²⁶ Th	4E+0 Bone surf	6E-3 Bone surf	3E-12	-	-	-
			(9E+0)	(2E-2)	-	2E-14	1E-7	1E-6
			-	(2E-2)	-	2E-14	1E-7	1E-6
		Y, see ²²⁶ Th	-	2E-2 Bone surf	6E-12	-	-	-
			-	2E-2 Bone surf	6E-12	-	-	-
90	Thorium-231	W, see ²²⁶ Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
			-	6E+3	3E-6	9E-9	-	-
			-	6E+3	3E-6	9E-9	-	-
		Y, see ²²⁶ Th	-	6E+3	3E-6	9E-9	-	-
			-	6E+3	3E-6	9E-9	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
90	Thorium-232	W, see ²²⁶ Th	7E-1	1E-3	5E-13	-	-	-
			Bone surf	Bone surf				
		(2E+0)	(3E-3)	-	4E-15	3E-8	3E-7	
		Y, see ²²⁶ Th	-	3E-3	1E-12	-	-	-
			Bone surf					
90	Thorium-234	W, see ²²⁶ Th	-	(4E-3)	-	6E-15	-	-
			3E+2	2E+2	8E-8	3E-10	-	-
		LLI wall	(4E+2)	-	-	-	5E-6	5E-5
		Y, see ²²⁶ Th	-	2E+2	6E-8	2E-10	-	-
91	Protactinium-227 ²	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91	Protactinium-228	W, see ²²⁷ Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
				Bone surf				
		-	(2E+1)	-	3E-11	-	-	
		Y, see ²²⁷ Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see ²²⁷ Pa	6E+2	5E+0	2E-9	7E-12	-	-
			Bone surf					
		(9E+2)	-	-	-	1E-5	1E-4	
		Y, see ²²⁷ Pa	-	4E+0	1E-9	5E-12	-	-
91	Protactinium-231	W, see ²²⁷ Pa	2E-1	2E-3	6E-13	-	-	-
			Bone surf	Bone surf				
		(5E-1)	(4E-3)	-	6E-15	6E-9	6E-8	
		Y, see ²²⁷ Pa	-	4E-3	2E-12	-	-	-
			Bone surf					
91	Protactinium-232	W, see ²²⁷ Pa	-	(6E-3)	-	8E-15	-	-
			1E+3	2E+1	9E-9	-	2E-5	2E-4
		Bone surf						
		Y, see ²²⁷ Pa	-	(6E+1)	-	8E-11	-	-
			6E+1	2E-8	-	-	-	
			Bone surf					
91	Protactinium-233	W, see ²²⁷ Pa	-	(7E+1)	-	1E-10	-	-
			1E+3	7E+2	3E-7	1E-9	-	-
		LLI wall	(2E+3)	-	-	-	E-5	2E-4
		Y, see ²²⁷ Pa	-	6E+2	2E-7	8E-10	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)	
91	Protactinium-234	W, see ²²⁷ Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ²²⁷ Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF, UOF, UO(NO)	4E+0	4E-1	2E-10	-	-	-
			Bone surf (6E+0)	Bone surf (6E-1)	-	8E-13	8E-8	8E-7
		W, UO, UF, UCl	-	4E-1	1E-10	5E-13	-	-
		Y, UO, UO	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see ²³⁰ U	5E+3 LLI wall	8E+3	3E-6	1E-8	-	-
			(4E+3)	-	-	-	6E-5	6E-4
		W, see ²³⁰ U	-	6E+3	2E-6	8E-9	-	-
		Y, see ²³⁰ U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see ²³⁰ U	2E+0	2E-1	9E-11	-	-	-
			Bone surf (4E+0)	Bone surf (4E-1)	-	6E-13	6E-8	6E-7
		W, see ²³⁰ U	-	4E-1	2E-10	5E-13	-	-
		Y, see ²³⁰ U	-	8E-3	3E-12	1E-14	-	-
92	Uranium-233	D, see ²³⁰ U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	7E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234 ³	D, see ²³⁰ U	1E+1	1E+0	5E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	7E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235 ³	D, see ²³⁰ U	1E+1	1E+0	6E-10	-	-	-
			Bone surf (2E+1)	Bone surf (2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	8E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	D, see ²³⁰ U	1E+1 Bone surf	1E+0 Bone surf	5E-10	-	-	-
			(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	8E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	6E-14	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
92 Uranium-237	D, see ²³⁰ U	2E+3 LLI wall	3E+3	1E-6	4E-9	-	-
		(2E+3)	-	-	-	3E-5	3E-4
	W, see ²³⁰ U	-	2E+3	7E-7	2E-9	-	-
	Y, see ²³⁰ U	-	2E+3	6E-7	2E-9	-	-
92 Uranium-238 ³	D, see ²³⁰ U	1E+1 Bone surf	1E+0 Bone surf	6E-10	-	-	-
		(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
	W, see ²³⁰ U	-	8E-1	3E-10	1E-12	-	-
	Y, see ²³⁰ U	-	4E-2	2E-11	6E-14	-	-
92 Uranium-239 ²	D, see ²³⁰ U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
	W, see ²³⁰ U	-	2E+5	7E-5	2E-7	-	-
	Y, see ²³⁰ U	-	2E+5	6E-5	2E-7	-	-
92 Uranium-240	D, see ²³⁰ U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see ²³⁰ U	-	3E+3	1E-6	4E-9	-	-
	Y, see ²³⁰ U	-	2E+3	1E-6	3E-9	-	-
92 Uranium-natural ³	D, see ²³⁰ U	1E+1 Bone surf	1E+0 Bone surf	5E-10	-	-	-
		(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
	W, see ²³⁰ U	-	8E-1	3E-10	9E-13	-	-
	Y, see ²³⁰ U	-	5E-2	2E-11	9E-14	-	-
93 Neptunium-232 ²	W, all compounds	1E+5	2E+3 Bone surf	7E-7	-	2E-3	2E-2
		-	(5E+2)	-	6E-9	-	-
93 Neptunium-233 ²	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93 Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93 Neptunium-235	W, all compounds	2E+4 LLI wall	8E+2 Bone surf	3E-7	-	-	-
		(2E+4)	(1E+3)	-	2E-9	3E-4	3E-3
93 Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf	2E-2 Bone surf	9E-12	-	-	-
		(6E+0)	(5E-2)	-	8E-14	9E-8	9E-7
93 Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf	3E+1 Bone surf	1E-8	-	-	-
		(4E+3)	(7E+1)	-	1E-10	5E-5	5E-4
93 Neptunium-237	W, all compounds	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
		(1E+0)	(1E-2)	-	1E-14	2E-8	2E-7
93 Neptunium-238	W, all compounds	1E+3	6E+1 Bone surf	3E-8	-	2E-5	2E-4
		-	(2E+2)	-	2E-10	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)
93	Neptunium-239	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 -	9E-7 -	3E-9 -	- 2E-5	- 2E-4
93	Neptunium-240 ²	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235 ²	W, see ²³⁴ Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ²³⁴ Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see ²³⁴ Pu	2E+0 Bone surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12 -	- 5E-14	- 6E-8	- 6E-7
		Y, see ²³⁴ Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see ²³⁴ Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ²³⁴ Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see ²³⁴ Pu	9E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ²³⁴ Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see ²³⁴ Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ²³⁴ Pu	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	-
94	Plutonium-240	W, see ²³⁴ Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ²³⁴ Pu	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	-
94	Plutonium-241	W, see ²³⁴ Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 -	- 8E-13	- 1E-6	- 1E-5
		Y, see ²³⁴ Pu	-	8E-1 Bone surf (1E+0)	3E-10 -	- 1E-12	- -	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio-nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
94	Plutonium-242	W, see ²³⁴ Pu	8E-1	7E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see ²³⁴ Pu	-	2E-2 Bone surf	7E-12	-	-	-
			-	(2E-2)	-	2E-14	-	-
94	Plutonium-243	W, see ²³⁴ Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see ²³⁴ Pu	-	4E+4	2E-5	5E-8	-	-
94	Plutonium-244	W, see ²³⁴ Pu	8E-1	7E-3	3E-12	-	-	-
			Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
		Y, see ²³⁴ Pu	-	2E-2 Bone surf	7E-12	-	-	-
			-	(2E-2)	-	2E-14	-	-
94	Plutonium-245	W, see ²³⁴ Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ²³⁴ Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see ²³⁴ Pu	4E+2 LLI wall (4E+2)	3E+2	1E-7	4E-10	-	-
			-	-	-	-	6E-6	6E-5
		Y, see ²³⁴ Pu	-	3E+2	1E-7	4E-10	-	-
95	Americium-237 ²	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238 ²	W, all compounds	4E+4	3E+3 Bone surf (6E+3)	1E-6	-	5E-4	5E-3
			-	-	9E-9	-	-	
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
			8E-1	6E-3	3E-12	-	-	-
95	Americium-242m	W, all compounds	Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
			8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (9E+1)	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
			-	-	-	-	-	-

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.		Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
95	Americium-244m ²	W, all compounds	6E+4	4E+3	2E-6	-	-	-
			St wall	Bone surf				
			(8E+4)	(7E+3)	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
				Bone surf				
			-	(3E+2)	-	4E-10	-	-
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m ²	W, all compounds	5E+4	2E+5	8E-5	3E-7	-	-
			St wall					
			(6E+4)	-	-	-	8E-4	8E-3
95	Americium-246 ²	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1	6E-1	2E-10	-	-	-
			Bone surf	Bone surf				
			(8E+1)	(6E-1)	-	9E-13	1E-6	1E-5
96	Curium-241	W, all compounds	1E+3	3E+1	1E-8	-	2E-5	2E-4
				Bone surf				
			-	(4E+1)	-	5E-11	-	-
96	Curium-242	W, all compounds	3E+1	3E-1	1E-10	-	-	-
			Bone surf	Bone surf				
			(5E+1)	(3E-1)	-	4E-13	7E-7	7E-6
96	Curium-243	W, all compounds	1E+0	9E-3	4E-12	-	-	-
			Bone surf	Bone surf				
			(2E+0)	(2E-2)	-	2E-14	3E-8	3E-7
96	Curium-244	W, all compounds	1E+0	1E-2	5E-12	-	-	-
			Bone surf	Bone surf				
			(3E+0)	(2E-2)	-	3E-14	3E-8	3E-7
96	Curium-245	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf	Bone surf				
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
96	Curium-246	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf	Bone surf				
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
96	Curium-247	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf	Bone surf				
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
96	Curium-248	W, all compounds	2E-1	2E-3	7E-13	-	-	-
			Bone surf	Bone surf				
			(4E-1)	(3E-3)	-	4E-15	5E-9	5E-8

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2		
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
96	Curium-249 ²	W, all compounds	5E+4	2E+4 Bone surf	7E-6	-	7E-4	7E-3
			-	(3E+4)	-	4E-8	-	-
96	Curium-250	W, all compounds	4E-2 Bone surf	3E-4 Bone surf	1E-13	-	-	-
			(6E-2)	(5E-4)	-	8E-16	9E-10	9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
97	Berkelium-249	W, all compounds	2E+2 Bone surf	2E+0 Bone surf	7E-10	-	-	-
			(5E+2)	(4E+0)	-	5E-12	6E-6	6E-5
97	Berkelium-250	W, all compounds	9E+3	3E+2 Bone surf	1E-7	-	1E-4	1E-3
			-	(7E+2)	-	1E-9	-	-
98	Californium-244 ²	W, all compounds except those given for Y	3E+4 St wall	6E+2	2E-7	8E-10	-	-
			(3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-
98	Californium-246	W, see ²⁴⁴ Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ²⁴⁴ Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see ²⁴⁴ Cf	8E+0 Bone surf	6E-2 Bone surf	3E-11	-	-	-
			(2E+1)	(1E-1)	-	2E-13	2E-7	2E-6
		Y, see ²⁴⁴ Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see ²⁴⁴ Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
		Y, see ²⁴⁴ Cf	-	1E-2 Bone surf	4E-12	-	-	-
			-	(1E-2)	-	2E-14	-	-
98	Californium-250	W, see ²⁴⁴ Cf	1E+0 Bone surf	9E-3 Bone surf	4E-12	-	-	-
			(2E+0)	(2E-2)	-	3E-14	3E-8	3E-7
		Y, see ²⁴⁴ Cf	-	3E-2	1E-11	4E-14	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic Radio- nuclide No.	Class	Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	Monthly Average
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			Concentration (μCi/ml)
98 Californium-251	W, see ²⁴⁴ Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
		(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
	Y, see ²⁴⁴ Cf	-	1E-2 Bone surf	4E-12	-	-	-
		-	(1E-2)	-	2E-14	-	-
98 Californium-252	W, see ²⁴⁴ Cf	2E+0 Bone surf	2E-2 Bone surf	8E-12	-	-	-
		(5E+0)	(4E-2)	-	5E-14	7E-8	7E-7
	Y, see ²⁴⁴ Cf	-	3E-2	1E-11	5E-14	-	-
98 Californium-253	W, see ²⁴⁴ Cf	2E+2 Bone surf	2E+0	8E-10	3E-12	-	-
		(4E+2)	-	-	-	5E-6	5E-5
	Y, see ²⁴⁴ Cf	-	2E+0	7E-10	2E-12	-	-
98 Californium-254	W, see ²⁴⁴ Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
	Y, see ²⁴⁴ Cf	-	2E-2	7E-12	2E-14	-	-
99 Einsteinium-250	W, all compounds	4E+4 Bone surf	5E+2	2E-7	-	6E-4	6E-3
		(1E+3)	-	2E-9	-	-	-
99 Einsteinium-251	W, all compounds	7E+3 Bone surf	9E+2	4E-7	-	1E-4	1E-3
		-	(1E+3)	-	2E-9	-	-
99 Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99 Einsteinium-254m	W, all compounds	3E+2 LLI wall	1E+1	4E-9	1E-11	-	-
		(3E+2)	-	-	-	4E-6	4E-5
99 Einsteinium-254	W, all compounds	8E+0 Bone surf	7E-2 Bone surf	3E-11	-	-	-
		(2E+1)	(1E-1)	-	2E-13	2E-7	2E-6
100 Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100 Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100 Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100 Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100 Fermium-257	W, all compounds	2E+1 Bone surf	2E-1 Bone surf	7E-11	-	-	-
		(4E+1)	(2E-1)	-	3E-13	5E-7	5E-6
101 Mendelevium- 257	W, all compounds	7E+3	8E+1 Bone surf	4E-8	-	1E-4	1E-3

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	INHALATION				Monthly Average
Atomic Radio- nuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
		-	(9E+1)	-	1E-10	-	-
101 Mendelevium- 258	W, all compounds	3E+1 Bone surf (5E+1)	2E-1 Bone surf (3E-1)	1E-10 -	- 5E-13	- 6E-7	- 6E-6
- Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours Submersion ¹		-	2E+2	1E-7	1E-9	-	-
- Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		-	2E-1	1E-10	1E-12	1E-8	1E-7
- Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radio-nuclide in the mixture is not known		-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:
¹"Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.
²These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (see 40.17)
³For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see 40.15(5)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:
SA = 3.6E-7 curies/gram U U-depleted
SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)²] E-6, enrichment ≥ 0.72
where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE:
1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

If it is known that Ac-227-D and Cm-250-W are not present	-	7E-4	3E-13	-	-	-
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present	-	7E-3	3E-12	-	-	-
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present	-	7E-2	3E-11	-	-	-

Atomic Radio- nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	DAC (μCi/ml)			
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present							
		-	7E-1	3E-10	-	-	-
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D,Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D, W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present							
		-	7E+0	3E-9	-	-	-
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W, Y, Cm-248-W, and Cm-250-W are not present							
		-	-	-	-	1E-14	-
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present							
		-	-	-	1E-13	-	-
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D, W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present							
		-	-	-	-	1E-12	-
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present							
		-	-	-	-	1E-6	1E-5

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 μm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 μCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 μCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B, Chapter 40 for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

EXAMPLE: If radionuclides "A," "B," and "C" are present in concentrations C_A , C_B , and C_C , and if the applicable DACs are DAC_A , DAC_B , and DAC_C , respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

[**ARC 8982B**, IAB 8/11/10, effective 9/15/10]

CHAPTER 40

APPENDIX C

QUANTITIES¹ OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μ Ci)*	Radionuclide	Quantity (μ Ci)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	100	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100

Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000
Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000

Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000		
Niobium-88	1,000	Palladium-101	1,000
Niobium-89m		Palladium-103	100
(66 min)	1,000	Palladium-107	10
Niobium-89		Palladium-109	100
(122 min)	1,000	Silver-102	1,000
Niobium-90	100	Silver-103	1,000
Niobium-93m	10	Silver-104m	1,000
Niobium-94	1	Silver-104	1,000
Niobium-95m	100	Silver-105	100
Niobium-95	100	Silver-106m	100
Niobium-96	100	Silver-106	1,000
Niobium-97	1,000	Silver-108m	1
Niobium-98	1,000	Silver-110m	10
Molybdenum-90	100	Silver-111	100
Molybdenum-93m	100	Silver-112	100
Molybdenum-93	10	Silver-115	1,000
Molybdenum-99	100	Cadmium-104	1,000
Molybdenum-101	1,000	Cadmium-107	1,000
Technetium-93m	1,000	Cadmium-109	1
Technetium-93	1,000	Cadmium-113m	0.1
Technetium-94m	1,000	Cadmium-113	100
Technetium-94	1,000	Cadmium-115m	10
Technetium-96m	1,000	Cadmium-115	100
Technetium-96	100	Cadmium-117m	1,000
Technetium-97m	100	Cadmium-117	1,000
Technetium-97	1,000	Indium-109	1,000
Technetium-98	10	Indium-110m	
Technetium-99m	1,000	(69.1m)	1,000
Technetium-99	100	Indium-110	
Technetium-101	1,000	(4.9h)	1,000
Technetium-104	1,000	Indium-111	100
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000

Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100		
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120		Iodine-131	1
(16m)	1,000	Iodine-132m	100
Antimony-120		Iodine-132	100
(5.76d)	100	Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128		Xenon-127	1,000
(10.4m)	1,000	Xenon-129m	1,000
Antimony-128		Xenon-131m	1,000
(9.01h)	100	Xenon-133m	1,000
Antimony-129	100	Xenon-133	1,000
Antimony-130	1,000	Xenon-135m	1,000

Antimony-131	1,000	Xenon-135	1,000
Tellurium-116	1,000	Xenon-138	1,000
Tellurium-121m	10	Cesium-125	1,000
Tellurium-121	100	Cesium-127	1,000
Tellurium-123m	10	Cesium-129	1,000
Tellurium-123	100	Cesium-130	1,000
Tellurium-125m	10	Cesium-131	1,000
Tellurium-127m	10	Cesium-132	100
Tellurium-127	1,000	Cesium-134m	1,000
Tellurium-129m	10	Cesium-134	10
Tellurium-129	1,000	Cesium-135m	1,000
Tellurium-131m	10	Cesium-135	100
Tellurium-131	100	Cesium-136	10
Tellurium-132	10	Cesium-137	10
Tellurium-133m	100	Cesium-138	1,000
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100

Cerium-143	100	Europium-150	
Cerium-144	1	(12.62h)	100
Praseodymium-136	1,000	Europium-150	
Praseodymium-137	1,000	(34.2y)	1
Praseodymium-138m	1,000	Europium-152m	100
Praseodymium-139	1,000	Europium-152	1
Praseodymium-142m	1,000	Europium-154	1
Praseodymium-142	100	Europium-155	10
Praseodymium-143	100	Europium-156	100
Praseodymium-144	1,000	Europium-157	100
Praseodymium-145	100	Europium-158	1,000
Praseodymium-147	1,000	Gadolinium-145	1,000
Neodymium-136	1,000	Gadolinium-146	10
Neodymium-138	100	Gadolinium-147	100
Neodymium-139m	1,000	Gadolinium-148	0.001
Neodymium-139	1,000	Gadolinium-149	100
Neodymium-141	1,000	Gadolinium-151	10
Neodymium-147	100	Gadolinium-152	100
Neodymium-149	1,000	Gadolinium-153	10
Neodymium-151	1,000	Gadolinium-159	100
Terbium-147	1,000	Ytterbium-162	1,000
Terbium-149	100	Ytterbium-166	100
Terbium-150	1,000	Ytterbium-167	1,000
Terbium-151	100	Ytterbium-169	100
Terbium-153	1,000	Ytterbium-175	100
Terbium-154	100	Ytterbium-177	1,000
Terbium-155	1,000	Ytterbium-178	1,000
Terbium-156m		Lutetium-169	100
(5.0h)	1,000	Lutetium-170	100
Terbium-156m		Lutetium-171	100
(24.4h)	1,000	Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10
Terbium-158	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100

Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000
Tantalum-182	10	Iridium-188	100
Tantalum-183	100	Iridium-189	100
Tantalum-184	100	Iridium-190m	1,000
Tantalum-185	1,000	Iridium-190	100
Tantalum-186	1,000	Iridium-192m	
Tungsten-176	1,000	(1.4m)	10
Tungsten-177	1,000	Iridium-192	
Tungsten-178	1,000	(73.8d)	1
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100
Rhenium-182		Platinum-193m	100
(12.7h)	1,000	Platinum-193	1,000

Rhenium-182		Platinum-195m	100
(64.0h)	100	Platinum-197m	1,000
Rhenium-184m	10	Platinum-197	100
Rhenium-184	100	Platinum-199	1,000
Rhenium-186m	10	Platinum-200	100
Rhenium-186	100	Gold-193	1,000
Rhenium-187	1,000	Gold-194	100
Rhenium-188m	1,000	Gold-195	10
Rhenium-188	100	Gold-198m	100
Rhenium-189	100	Gold-198	100
Osmium-180	1,000	Gold-199	100
Osmium-181	1,000	Gold-200m	100
Osmium-182	100	Gold-200	1,000
Osmium-185	100	Gold-201	1,000
Osmium-189m	1,000	Mercury-193m	100
Osmium-191m	1,000	Mercury-193	1,000
Osmium-191	100	Mercury-194	1
Osmium-193	100	Mercury-195m	100
Osmium-194	1	Mercury-195	1,000
Iridium-182	1,000	Mercury-197m	100
Iridium-184	1,000	Mercury-197	1,000
Iridium-185	1,000	Mercury-199m	1,000
Iridium-186	100	Mercury-203	100
Iridium-187	1,000		
Thallium-194m	1,000	Francium-223	100
Thallium-194	1,000	Radium-223	0.1
Thallium-195	1,000	Radium-224	0.1
Thallium-197	1,000	Radium-225	0.1
Thallium-198m	1,000	Radium-226	0.1
Thallium-198	1,000	Radium-227	1,000
Thallium-199	1,000	Radium-228	0.1
Thallium-200	1,000	Actinium-224	1
Thallium-201	1,000	Actinium-225	0.01
Thallium-202	100	Actinium-226	0.1
Thallium-204	100	Actinium-227	0.001
Lead-195m	1,000	Actinium-228	1
Lead-198	1,000	Thorium-226	10
Lead-199	1,000	Thorium-227	0.01
Lead-200	100	Thorium-228	0.001
Lead-201	1,000	Thorium-229	0.001
Lead-202m	1,000	Thorium-230	0.001
Lead-202	10	Thorium-231	100

Lead-203	1,000	Thorium-232	100
Lead-205	100	Thorium-234	10
Lead-209	1,000	Thorium-natural	100
Lead-210	0.01	Protactinium-227	10
Lead-211	100	Protactinium-228	1
Lead-212	1	Protactinium-230	0.1
Lead-214	100	Protactinium-231	0.001
Bismuth-200	1,000	Protactinium-232	1
Bismuth-201	1,000	Protactinium-233	100
Bismuth-202	1,000	Protactinium-234	100
Bismuth-203	100	Uranium-230	0.01
Bismuth-205	100	Uranium-231	100
Bismuth-206	100	Uranium-232	0.001
Bismuth-207	10	Uranium-233	0.001
Bismuth-210m	0.1	Uranium-234	0.001
Bismuth-210	1	Uranium-235	0.001
Bismuth-212	10	Uranium-236	0.001
Bismuth-213	10	Uranium-237	100
Bismuth-214	100	Uranium-238	100
Polonium-203	1,000	Uranium-239	1,000
Polonium-205	1,000	Uranium-240	100
Polonium-207	1,000	Uranium-natural	100
Polonium-210	0.1	Neptunium-232	100
Astatine-207	100	Neptunium-233	1,000
Astatine-211	10	Neptunium-234	100
Radon-220	1	Neptunium-235	100
Radon-222	1	Neptunium-236	
Francium-222	100	(1.15E+5)	0.001
Neptunium-236		Curium-242	0.01
(22.5h)	1	Curium-243	0.001
Neptunium-237	0.001	Curium-244	0.001
Neptunium-238	10	Curium-245	0.001
Neptunium-239	100	Curium-246	0.001
Neptunium-240	1,000	Curium-247	0.001
Plutonium-234	10	Curium-248	0.001
Plutonium-235	1,000	Curium-249	1,000
Plutonium-236	0.001	Berkelium-245	100
Plutonium-237	100	Berkelium-246	100
Plutonium-238	0.001	Berkelium-247	0.001
Plutonium-239	0.001	Berkelium-249	0.1
Plutonium-240	0.001	Berkelium-250	10
Plutonium-241	0.01	Californium-244	100

Plutonium-242	0.001	Californium-246	1
Plutonium-243	1,000	Californium-248	0.01
Plutonium-244	0.001	Californium-249	0.001
Plutonium-245	100	Californium-250	0.001
Americium-237	1,000	Californium-251	0.001
Americium-238	100	Californium-252	0.001
Americium-239	1,000	Californium-253	0.1
Americium-240	100	Californium-254	0.001
Americium-241	0.001	Einsteinium-250	100
Americium-242m	0.001	Einsteinium-251	100
Americium-242	10	Einsteinium-253	0.1
Americium-243	0.001	Einsteinium-254m	1
Americium-244m	100	Einsteinium-254	0.01
Americium-244	10	Fermium-252	1
Americium-245	1,000	Fermium-253	1
Americium-246m	1,000	Fermium-254	10
Americium-246	1,000	Fermium-255	1
Curium-238	100	Fermium-257	0.01
Curium-240	0.1	Mendelevium-257	10
Curium-241	1	Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

*To convert μCi to kBq , multiply the μCi value by 37.

¹The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to this chapter, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 μCi). Values of 3.7 MBq (100 μCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000 μCi), to take into account their low specific activity.

NOTE: For purposes of 40.61(5), 40.64(1), and 40.95(1) where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1"—that is, unity.

CHAPTER 40

APPENDIX D

REQUIREMENTS FOR TRANSFERS AND MANIFESTS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES

As used in this appendix, the following definitions apply:

“Chelating agent” means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

“Chemical description” means a description of the principal chemical characteristics of a low-level radioactive waste.

“Computer-readable medium” means that the regulatory agency’s computer can transfer the information from the medium into its memory.

“Consignee” means the designated receiver of the shipment of low-level radioactive waste.

“Decontamination facility” means a facility operating under an agreement state or Nuclear Regulatory Commission license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives and, for purposes of this appendix, is not considered to be a consignee for LLW shipments.

“Disposal container” means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see “high integrity container”). Note that for some shipments, the disposal container may be the transport package.

“EPA identification number” means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263.

“Forms 540, 540A, 541, 541A, 542, and 542A” are official forms referenced in this appendix. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Forms 541 (and 541A) and Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

“Generator” means a licensee operating under an agreement state or Nuclear Regulatory Commission license who (1) is a waste generator as defined in this rule, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

“High integrity container (HIC)” means a container commonly designed to meet the structural stability requirements of 10 CFR 61.56, and to meet United States Department of Transportation requirements for a Type A package.

“Land disposal facility” means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this appendix, a “geologic repository” as defined in 10 CFR Part 60 is not considered a land disposal facility.

“Package” means the assembly of components necessary to ensure compliance with the packaging requirements of United States Department of Transportation regulations, together with its radioactive contents, as presented for transport.

“Physical description” means the items called for on Form 541 to describe a low-level radioactive waste.

“Residual waste” means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

“Shipper” means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

“Shipping paper” means Form 540 and, if required, Form 540A which includes the information required by United States Department of Transportation in 49 CFR Part 172.

“Uniform Low-Level Radioactive Waste Manifest” or “uniform manifest” means the combination of Forms 540, 541 and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

“Waste collector” means an entity, operating under an agreement state or Nuclear Regulatory Commission license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

“Waste description” means the physical, chemical and radiological description of a low-level radioactive waste as called for on Form 541.

“Waste generator” means an entity, operating under an agreement state or Nuclear Regulatory Commission license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a “waste generator” if the transfer of low-level radioactive waste from its facility is defined as “residual waste.”

“Waste processor” means an entity, operating under an agreement state or Nuclear Regulatory Commission license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

“Waste type” means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by this agency to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the “waste generator” or “generator,” as defined in this part; or

(c) Radioactively contaminated material to a “waste processor” that becomes the processor’s “residual waste.”

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0111, telephone (301) 415-5877 or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

This appendix includes information requirements of the United States Department of Transportation, as codified in 49 CFR Part 172. Information on hazardous, medical, or other waste required to meet Environmental Protection Agency regulations, as codified in 40 CFR Parts 259, 261, or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

Information Requirements

A. General Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility's address, and telephone number of the licensee shipping the waste;
2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and
3. The name, address, and telephone number, or the name and EPA identification number, for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;
 2. The total number of packages/disposal containers;
 3. The total disposal volume and disposal weight in the shipment;
 4. The total radionuclide activity in the shipment;
 5. The activity of each of the radionuclides, H-3, C-14, Tc-99, and I-129 contained in the shipment;
- and
6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;
3. The volume displaced by the disposal container;
4. The gross weight of the disposal container, including the waste;
5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;
6. A physical and chemical description of the waste;
7. The total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;
8. The approximate volume of waste within a container;
9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;
10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;
11. The total radioactivity within each container; and
12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;
2. A physical and chemical description of the waste;
3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1 percent by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multigenerator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this appendix.) It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained in these waste types within the disposal container. For each generator, provide the following:

- (a) The volume of waste within the disposal container;
- (b) A physical and chemical description of the waste, including the solidification agent, if any;
- (c) The total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;
- (d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and
- (e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the United States Department of Transportation and this agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1. through A.9. of this appendix. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4. through A.9. of this appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with 10 CFR 61.55;

3. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program must include management evaluation of audits);

4. Prepare the Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the

manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

6. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5. of this section;

7. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41); and

9. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

4. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3. of this section;

5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

7. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph E.1. of this appendix;

3. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR 61.55 and 61.57;

5. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

7. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6. of this section;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and this agency of any shipment, or part of a shipment, that has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the license is terminated; and

3. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with this agency. Each licensee who conducts a trace investigation shall file a written report with this agency within two weeks of completion of the investigation.

CHAPTER 40

APPENDIX E

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL
RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b) Classes of waste.

1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II. (a). If Class A waste also meets the stability requirements set forth in Section II. (b), it is not necessary to segregate the waste for disposal.

2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE I

Radionuclide	Concentration	
	curie/cubic meter ^a	nanocurie/gram ^b
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	

Tc-99	3
I-129	0.08
Alpha emitting transuranic radionuclides with half-life greater than five years	100
Pu-241	3,500
Cm-242	20,000
Ra-226	100

^a To convert the Ci/m³ values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m³ value by 37.

^bTo convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Section I.(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

1) If the concentration does not exceed the value in Column 1, the waste is Class A.

2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE II

Radionuclide	Concentration, Column 1	curie/cubic meter *	
		Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

*AGENCY NOTE: To convert the Ci/m³ value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m³ value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

g) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

h) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m³ (50 Ci/m³) and Cs-137 in a concentration of 814 GBq/m³ (22 Ci/m³). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, $50/150 = 0.33$; for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

II. Radioactive Waste Characteristics

a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of this chapter, the site license conditions shall govern.

2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4) Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

7) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.⁴

8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 100 Ci (3.7 TBq) per container.

⁴See 641—38.2 of these rules for the definition of pyrophoric.

9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself,

processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2) Notwithstanding the provisions in Section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

CHAPTER 40

APPENDIX F

QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100

<u>Material</u>	<u>Microcurie*</u>
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100

<u>Material</u>	<u>Microcurie*</u>
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10

<u>Material</u>	<u>Microcurie*</u>
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10

<u>Material</u>	<u>Microcurie*</u>
Tungsten-185	10
Tungsten-187	100
Uranium (natural)**	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha-emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

*To convert μCi to kBq , multiply the μCi value by 37.

**Based on alpha disintegration rate of U-238, U-234, and U-235.

NOTE: This Appendix is retained for use by those agreement states that need to adopt decommissioning regulations compatible with the U.S. Nuclear Regulatory Commission.

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1"—that is, unity.

CHAPTER 40

APPENDIX G

RADIONUCLIDES OF CONCERN

Rescinded **ARC 1479C**, IAB 6/11/14, effective 7/16/14

APPENDIX H

NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16.0
Americium-241/Be	60	1,600	0.6	16.0
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14.0
Cesium-137	100	2,700	1.0	27.0
Gadolinium-153	1,000	27,000	10.0	270.0
Iridium-192	80	2,200	0.8	22.0
Plutonium-238	60	1,600	0.6	16.0
Plutonium-239/Be	60	1,600	0.6	16.0
Polonium-210	60	1,600	0.6	16.0
Promethium-147	40,000	1,100,000	400.0	11,000.0
Radium-226	40	1,100	0.4	11.0
Selenium-75	200	5,400	2.0	54.0
Strontium-90	1,000	27,000	10.0	270.0
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200.0	5,400.0
Ytterbium-169	300	8,100	3.0	81.0

These rules are intended to implement Iowa Code chapter 136C.

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CHAPTER 41
SAFETY REQUIREMENTS FOR THE USE OF
RADIATION MACHINES AND CERTAIN USES
OF RADIOACTIVE MATERIALS

641—41.1(136C) X-rays in the healing arts.

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of November 5, 2014.

41.1(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 and 40 may also apply. The following are specific to 641—Chapter 41.

“Accessible surface” means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

“Added filtration” means any filtration which is in addition to the inherent filtration.

“Aluminum equivalent” means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

“Attenuation block” means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

“Automatic exposure control (AEC)” means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also “Phototimer”). (Includes devices such as phototimers and ion chambers.)

“Base density” means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

“Base plus fog density” means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

“Beam monitoring system” means a system designed to detect and measure the radiation present in the useful beam.

“C-arm X-ray system” means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

“Cassette” means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

“Cephalometric device” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“Certified components” means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the “Radiation Control for Health and Safety Act of 1968,” the Food and Drug Administration.

“Certified system” means any X-ray system which has one or more certified component(s).

“Coefficient of variation” or *“C”* means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

\bar{s} = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample.

“Computed tomography” means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

“Control chart” means a chart used to record (and control) the results of quality control testing as a function of time.

“Control limit” means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

“Control panel” (see X-ray control panel).

“Cooling curve” means the graphical relationship between heat units stored and cooling time.

“CT” (see “Computed tomography”).

“Dead-man switch” means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

“Dedicated mammography equipment” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“Densitometer” means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

“Detents” means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

“Developer” means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

“Developer replenishment” means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

“Diagnostic mammography” means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

“Diagnostic source assembly” means the tube housing assembly with a beam-limiting device attached.

“Direct scattered radiation” means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see “Scattered radiation”).

“Entrance exposure rate” means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

“Equipment” (see “X-ray equipment”).

“Field emission equipment” means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

“Filter” means material placed in the useful beam to preferentially absorb selected radiations.

“Fixer” means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

“Fixer retention” means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

“Fluoroscopic imaging assembly” means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical

interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

“Focal spot (actual)” means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

“Focal spot size” means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

“Fog” means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

“General purpose radiographic X-ray system” means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

“Gonad shield” means a protective barrier for the testes or ovaries.

“Healing arts screening” means the use of radiation on human beings for the detection or evaluation of health indicators for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under 41.1(3)“a”(7), or
2. An individual licensed as a physician in Iowa and listed as an authorized user on an NRC or agreement state radioactive materials license.

“Heat unit” means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., $kVp \times mA \times \text{second}$.

“Image contrast” means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attenuation difference or light exposure difference.

“Image intensifier” means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

“Image noise” See “Radiographic noise.”

“Image quality” means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

“Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

“Image sharpness” means the overall impression of detail and clarity in a radiographic image.

“Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

“Kilovolts peak” (see “Peak tube potential”).

“kVp” (see “Peak tube potential”).

“kWs” means kilowatt second.

“Leakage technique factors” means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

“Linear attenuation coefficient” or “ μ ” means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

“Line-voltage regulation” means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where

V_n = No-load line potential and

V_l = Load line potential.

“mAs” means milliamperere second.

“Maximum line current” means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

“Mobile X-ray equipment” (see “X-ray equipment”).

“PBL” (see “Positive beam limitation”).

“Phototimer” means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see “Automatic exposure control”).

“PID” (see “Position indicating device”).

“Portable X-ray equipment” (see “X-ray equipment”).

“Position indicating device” means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

“Positive beam limitation” means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

“Processor” means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

“Protective apron” means an apron made of radiation-absorbing materials used to reduce radiation exposure.

“Protective glove” means a glove made of radiation-absorbing materials used to reduce radiation exposure.

“Quality assurance” means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

“Quality control” means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

“Radiation therapy simulation system” means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

“Radiograph” means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

“Radiographic contrast” means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amount of X-ray or visible light exposure.

“Radiographic noise” means unwanted fluctuations in optical density on the screen-film image.

“Rating” means the operating limits as specified by the component manufacturer.

“Recording” means producing a permanent form of an image resulting from X-ray photons.

“Repeat (or reject) analysis” means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

“Replenishment rate” means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

“Response time” means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

“Safelight” means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

“Screen” means microscopic phosphor crystals on a plastic support used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

“Screen-film combination” means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

“Screen-film contact” means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

“Sensitometer” means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

“Sensitometric strip” means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

“Sensitometry” means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

“SID” (see “Source-image receptor distance”).

“Source” means the focal spot of the X-ray tube.

“Source-image receptor distance” means the distance from the source to the center of the input surface of the image receptor.

“Spot check” means a procedure which is performed to ensure that a previous calibration continues to be valid.

“Spot film” means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

“Spot-film device” means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

“Stationary X-ray equipment” (see “X-ray equipment”).

“Technique factors” means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“Tomogram” means the depiction of the X-ray attenuation properties of a section through the body.

“Tube rating chart” means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

“Useful beam” means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

“Variable-aperture beam-limiting device” means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

“Viewbox” means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

“Visible area” means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

“X-ray control panel” means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

“X-ray equipment” means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. *“Mobile X-ray equipment”* means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. *“Portable X-ray equipment”* means X-ray equipment designed to be hand-carried.

c. *“Stationary X-ray equipment”* means X-ray equipment which is installed in a fixed location.

“X-ray exposure control” means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

“X-ray field” means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

“X-ray high-voltage generator” means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

“X-ray system” means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

“X-ray table” means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

41.1(3) Administrative controls.

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant’s administrative control, for ensuring that the requirements of these rules are met in the operation of the X-ray system(s), and for having the following minimum tests performed by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.

3. Fluoroscopic: entrance exposure rate (41.1(5) “c”), and minimum SSD (41.1(5) “f”) annually.

4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant’s agent shall ensure that the requirements of these rules are met in the operation of the X-ray system(s).

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

1. Operators in medical facilities shall meet the requirements of 641—Chapter 42, as applicable, and shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;

2. Type and size of the film or film-screen combination to be used;

3. Type and focal distance of the grid to be used, if any;

4. Source to image receptor distance to be used, except for dental intra-oral radiography; and

5. Type and location of placement of human patient shielding to be used (e.g., gonad).

(4) Written safety procedures shall be provided to each individual operating X-ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

2. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3) "a"(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3) "a"(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3) "a"(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3) "a"(5) "2";

4. No individual shall be used routinely to hold film or patients; and
5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(4) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the applicant shall notify the agency in writing within five calendar days.

(12) Rescinded IAB 3/31/04, effective 5/5/04.

b. Information and maintenance record and associated information. Records in 41.1(3) “b”(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3) “b”(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

- (1) User’s manual for the X-ray system;
- (2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;
- (3) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient’s name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

2. Processing deviations from the requirements of 41.1(3)“f” shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

3. All processing equipment shall be in good mechanical working order.

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3) "f" are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

41.1(4) General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 $\mu\text{C/kg}$) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 $\mu\text{C/kg}$) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Rescinded IAB 4/8/98, effective 7/1/98.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)“e” shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)“e”(1)“1” is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)“h”(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator’s position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer's standards.

i. Rescinded IAB 3/30/05, effective 5/4/05.

41.1(5) *Fluoroscopic X-ray systems except for computed tomography X-ray systems.* All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5) "a"(2)"1" apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;

- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;

- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5) "a"(2) and 41.1(5) "a"(3), that means:

1. Shall be designed for use only in the event of system failure;
2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except

- During recording of fluoroscopic images; or
- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5) "c" shall be determined as follows:

- If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;
- If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

- All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

- For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5) "c"(1)"3";
- The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5) "c"(1)"3."

(2) Reserved.

d. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μ C/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source-to-skin distance. The SSD shall not be less than:

- (1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,
- (2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,
- (3) 30 centimeters on all mobile fluoroscopes, and
- (4) 20 centimeters for mobile fluoroscopes used for specific surgical application.
- (5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)“a”(4).

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

h. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or
2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)“a”(5).

(3) The agency may grant exemptions to 41.1(5)“h”(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot-film exposure reproducibility. Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6)“d” when operating in the spot-film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)“a,” “c,” “d,” and “g” provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of 41.1(5)“g” are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. Dose-area-product monitor requirements.

(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

(2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If

a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the patient's physician must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

(3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

l. Equipment operation.

(1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(3) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22(136C).

n. Supervision of fluoroscopy. The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner or an advanced registered nurse practitioner (ARNP), pursuant to 655—subrule 7.2(2), for the purpose of localization to obtain images for diagnostic or therapeutic purposes. The use of fluoroscopy by radiologist assistants shall be as defined in 641—42.6(136C).

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6)“h”(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.

- Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.

- The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)“a”(1)“1” and “2” provided the registrant makes a written application for such exemption and in that application

demonstrates it is impractical to comply with 41.1(6)“a”(1)“1” and “2”; and the purpose of 41.1(6)“a”(1)“1” and “2” will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)“a”(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems designed for or provided with special attachments for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

(5) X-ray systems other than those described in 41.1(6)“a”(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.

1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

3. 41.1(6)“a”(5)“1” and “2” may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)“a”(1) or, when alignment means are also provided, may be met with either:

- An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

- A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a “zero” or “off” position if

either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to “zero.”

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6) “b”(2) “2”; or

- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure. Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. The X-ray control shall provide visual indication observable at or from the operator’s protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in 41.1(6) “b”(3) “2” shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6) “b”(3) “4,” and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (\bar{T}) shall be greater than or equal to five times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when four timer tests are performed:

$$\bar{T} \geq 5 (T_{\max} - T_{\min})$$

(5) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C kg⁻¹s⁻¹ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average $C \text{ kg}^{-1}\text{s}^{-1}$ (mR/s) values.

c. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters except for veterinary systems.

d. Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens ($0.516 \mu\text{C/kg}$) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliamperere-seconds product ($C \text{ kg}^{-1}\text{mAs}^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of mR/mAs (or $C \text{ kg}^{-1}\text{mAs}^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

h. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam limitation for stationary and mobile general purpose X-ray systems.

1. There shall be provided a means of stepless adjustment of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less.

The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(2) Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X-rays when

- Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 41.1(6) "h"(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or
- The sum of the length and width differences as stated in 41.1(6) "h"(2)"1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6) "h"(2)"1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6) "h"(2)"1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 41.1(6) "a" or 41.1(6) "h"(2).

i. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

j. Systems used in a clinical (nonsurgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3) "d."

41.1(7) Intraoral dental radiographic systems. In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used.

a. *Source-to-skin distance.* X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

- (1) 18 centimeters if operable above 50 kVp, or
- (2) 10 centimeters if not operable above 50 kVp.

b. *Beam limitation.* Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

- (1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and
- (2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4) "c."

c. *Exposure control.*

- (1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a “zero” or “off” position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator’s protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero.”

3. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half ($\frac{1}{2}$) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C\ kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operator. The procedures required under 41.1(3) “a”(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7) “c”(5) “1.”

- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly while making exposure.

3. Portable or hand-held dental X-ray systems designed with a backscatter shield may be used without the additional protective barrier, but the operator must wear a protective apron. The operator must stand directly behind the unit to allow the shield to function as designed.

d. *Reproducibility.* When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. *mA/mS linearity.* The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of $C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliamperere-seconds product, in units of $C\ kg^{-1}\ mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. kVp limitations. Dental X-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. Administrative controls.

- (1) Patient and film holding devices shall be used when the techniques permit.
- (2) The tube housing and the PID shall not be hand-held during an exposure.
- (3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7) "b"(1).

(4) Dental fluoroscopy without image intensification shall not be used.

i. Portable or hand-held dental X-ray systems. Portable or hand-held dental X-ray systems designed with a backscatter shield shall:

- (1) Be used only where it is impractical to use a portable dental system;
- (2) Be used as the manufacturer indicates;
- (3) Not be used with the backscatter shield removed, if applicable; and
- (4) Be exempted from 41.1(4) "g."

41.1(8) Rescinded IAB 6/4/97, effective 7/9/97.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges, OSL devices, or TLDs must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months and another request for discontinuance submitted to the agency.

c. Rescinded IAB 2/6/13, effective 3/13/13.

d. Specific operating procedures must be prepared and made available at the operator's position.

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

- (1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer's specifications. Records of maintenance shall be kept for inspection by the agency.

41.1(10) Veterinary medicine radiographic installations.

a. Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4) "c."

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. Operator protection.

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 40.21(136C) and subrule 40.26(1).

(2) All stationary, mobile or portable X-ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Operating procedures. Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1(136C) except for 641—subrules 41.1(3) and 41.1(10).

(1) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) Computed tomography X-ray systems.

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

"Computed tomography dose index" means the integral from $-7T$ to $+7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

$D(z)$ = Dose at position z .

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around $z = 0$ and that, for a multiple tomogram system, the scan increment between adjacent scans is nT .

“*Contrast scale*” means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

\overline{CTN}_x = of the material of interest.

\overline{CTN}_w = of water.

“CS” (see “Contrast scale”).

“*CT conditions of operation*” means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

“*CTDI*” (see “Computed tomography dose index”).

“*CT gantry*” means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

“*CTN*” (see “CT number”).

“*CT number*” means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.)

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

“*Dose profile*” means the dose as a function of position along a line.

“*Elemental area*” means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also “Picture element”).

“*Multiple tomogram system*” means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

“*Noise*” means the standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

\overline{CS} = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

“*Nominal tomographic section thickness*” means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

“*Picture element*” means an elemental area of a tomogram.

“*Reference plane*” means a plane which is displaced from and parallel to the tomographic plane.

“Scan” means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

“Scan increment” means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

“Scan sequence” means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

“Scan time” means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

“Single tomogram system” means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

“Tomographic plane” means that geometric plane which is identified as corresponding to the output tomogram.

“Tomographic section” means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

b. Requirements for equipment.

(1) Termination of exposure.

1. Means shall be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by 41.1(11) “b”(1)“1.”

3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.

(2) Tomographic plane indication and alignment.

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy 41.1(11) “b”(2)“1” or “2,” the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-on and shutter status indicators and control switches.

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4) “c.”

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

2. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. Facility design requirements.

(1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

1. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

2. The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

5. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI_{1/4} along the two axes specified in 41.1(11)“d”(2)“4” shall be measured. (For the purpose of determining the CTDI, the manufacturer’s statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)“d”(3) shall be made.

7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

(3) Spot checks.

1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. All spot checks shall be included in the calibration required by 41.1(11)“d”(2) and at time intervals and under system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)“d”(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X-ray system.

5. Written records of the spot checks performed shall be maintained for inspection by the agency.

(4) Operating procedures.

1. The CT X-ray system shall not be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 42.

41.1(12) X-ray machines used for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

[ARC 8659B, IAB 4/7/10, effective 5/12/10; ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—41.2(136C) Use of radionuclides in the healing arts.

41.2(1) Purpose and scope.

a. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of November 5, 2014.

41.2(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

“Area of use” means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

“Authorized medical physicist” means an individual who:

a. Meets the requirements of 41.2(74) and 41.2(77); or

b. Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license issued by this agency, the NRC, or an agreement state;
2. A medical use permit issued by an NRC master material licensee;
3. A permit issued by an NRC or agreement state broad scope medical use licensee; or
4. A permit issued by an NRC master material license broad scope medical use permittee.

“Authorized nuclear pharmacist” means a pharmacist who:

a. Has met the appropriate requirements of 41.2(77) and 41.2(78), or before May 3, 2006, meets the requirements in 10 CFR 35.980(a) and 10 CFR 35.59; or:

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;
2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29) “j”(2)“3.”

“Authorized user” means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67)“a,” 41.2(68)“a,” 41.2(69)“a,” 41.2(70)“a,” 41.2(72)“a,” 41.2(73)“a,” 41.2(81)“a,” or 41.2(82)“a,” or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;

2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or

4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

“Dedicated check source” means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

“Management” means the chief executive officer or that individual’s designee.

“Medical institution” means an organization in which several medical disciplines are practiced.

“Mobile nuclear medicine service” means the transportation and medical use of radioactive material.

“Output” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

“Pharmacist” means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

“Radiation safety officer” means an individual who, in addition to the definition in 641—38.2(136C), meets the requirements of 41.2(77) and 41.2(65)“a,” or 41.2(65)“c”(1), or before May 3, 2006, meets the requirements in 10 CFR 35.900(a) and 10 CFR 35.59; or is identified as a radiation safety officer on a specific medical use license issued by Iowa, the NRC, or agreement state or a medical use permit issued by an NRC master material licensee.

“Teletherapy physicist” means an individual identified as the qualified teletherapy physicist on an agency license.

“Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“Visiting authorized user” means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) License required.

a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28) “b” may apply for a Type A specific license of broad scope.

41.2(4) License amendments. A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this rule;

b. Before permitting anyone, except a visiting authorized user or visiting authorized nuclear pharmacist described in 41.2(12), to work as an authorized user or authorized nuclear pharmacist under the license;

c. Before changing a radiation safety officer, teletherapy physicist or authorized medical physicist;

d. Before receiving radioactive material in excess of the amount authorized on the license;

e. Before adding to or changing the address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

41.2(5) Notifications.

a. A licensee shall provide to the agency a copy of the board certification, the NRC or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as a visiting authorized user or a visiting authorized nuclear pharmacist.

b. A licensee shall notify the agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee’s mailing address changes.

c. The licensee shall mail the documents required in this subrule to the Iowa Department of Public Health, Des Moines, Iowa.

d. Exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provision of 41.2(4) “b”;

(2) The provisions of 41.2(4) “e” regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provision of 41.2(5) “a”;

(4) The provisions of 41.2(5) “b”(1) for authorized user or an authorized nuclear pharmacist.

41.2(6) Maintenance of records.

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6) “a” and “b.”

41.2(7) ALARA program.

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7) “a”:

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9) “b”(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) Radiation safety officer.

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee’s radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;

2. Receiving and opening packages of radioactive material;

3. Storing radioactive material;
 4. Keeping an inventory record of radioactive material;
 5. Using radioactive material safely;
 6. Taking emergency action if control of radioactive material is lost;
 7. Performing periodic radiation surveys;
 8. Performing checks and calibrations of survey instruments and other safety equipment;
 9. Disposing of radioactive material;
 10. Training personnel who work in or frequent areas where radioactive material is used or stored;
- and

11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) Radiation safety committee. Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) Rescinded IAB 10/1/14, effective 11/5/14.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;
2. Members present;
3. Members absent;
4. Summary of deliberations and discussions;
5. Recommended actions and the numerical results of all ballots; and
6. Document any reviews required in 41.2(7) "c" and 41.2(9) "b."

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review:

1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

2. Review on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) *Authority and responsibilities for the radiation protection program.*

a. In addition to the radiation protection program requirements of 641—40.10(136C), a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to this agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment.

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

c. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer under 41.2(65) or 41.2(75) to function as a temporary radiation safety officer to perform the functions of radiation safety officer, as provided in 41.2(10) "g," if the licensee takes the actions required in 41.2(10) "b," "e," "g," and "h" and notifies this agency in accordance with 41.2(5).

d. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with 41.2(10) "c" if needed to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of by-product material permitted on the license.

e. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

f. Licensees that are authorized for two or more different types of uses of radioactive materials or two or more types of units under this rule shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

g. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective solutions;

(3) Verify implementation of corrective actions; and

(4) Stop unsafe operations.

h. A licensee shall retain a record of actions taken under 41.2(10) in accordance with 641—40.80(136C).

41.2(11) *Supervision.*

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of this chapter, and license conditions appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals certified and issued a current permit to practice in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa-licensed physician and designated by the authorized user, shall be permitted to administer radionuclides (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, the individual's permit to practice shall be made available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user for the medical uses of by-product material;

(2) Follow the written radiation protection and written directive procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3) "c," shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user and visiting authorized nuclear pharmacist.*

a. A licensee may permit any visiting authorized user or visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user or visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user or visiting authorized nuclear pharmacist by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user or visiting authorized nuclear pharmacist is specifically authorized by an agency (agreement state, licensing state or U.S. Nuclear Regulatory Commission) license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12) "a."

c. A licensee shall retain copies of the records specified in 41.2(12) "a" for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material and clearly delineates the authority of the licensee and client.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

e. Mobile nuclear medicine service licensees shall also perform the following:

(1) Check instruments used to measure the activity of unsealed radioactive material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this rule must include a constancy check;

(2) Check survey instruments for proper operation with a dedicated check source before use at each client's address;

(3) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements of 641—Chapters 40 and 41.

41.2(14) *Records and reports of misadministrations and reportable medical events.*

a. When a misadministration or reportable medical event, as defined in 641—38.2(136C), occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient's or human research subject's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration or reportable medical event. If the referring physician, patient or human research subject, or the patient's or human research subject's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient's or human research subject's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the misadministration or reportable medical event because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration or reportable medical event. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or the human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration or reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. A copy of the report that was submitted to the agency; or

2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. Rescinded IAB 4/4/01, effective 5/9/01.

d. Each licensee shall retain a record of each misadministration for ten years and each reportable medical event for three years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14) "a" to 41.2(14) "d" shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of by-product material or radiation from by-product material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of by-product material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

1. The written report must include:

- The licensee's name;
- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14) "f"(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:
 - Name of the pregnant individual or the nursing child who is the subject of the event; and

- Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

41.2(15) *Suppliers.* A licensee shall use for medical use only:

- a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and

- b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;

- c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) *Quality control of imaging equipment.* Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) *Possession, use, calibration, and check of dose calibrators.*

- a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

- b. A licensee shall:

- (1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on frequently used settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

- (2) Test each dose calibrator for accuracy upon installation and at 12-month intervals thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

- (3) Test each dose calibrator for linearity upon installation and at 3-month intervals thereafter over the range of use between 30 microcuries (1.1 megabecquerels) and the highest dosage that will be administered; and

- (4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

- c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

- d. A licensee shall also perform checks and tests required by 41.2(17) "b" following adjustment or repair of the dose calibrator.

- e. A licensee shall retain a record of each check and test required by 41.2(17) for three years. The records required by 41.2(17) "b" shall include:

- (1) For 41.2(17) "b"(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

- (2) For 41.2(17) "b"(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17) “b”(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17) “b”(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) Calibration and check of survey instruments.

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18) “a,” the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18) “b,” the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18) “a” for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18) “a,” “b,” and “c,” the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18) “e” shall be maintained by the licensee.

g. Rescinded IAB 8/1/07, effective 9/5/07.

41.2(19) Assay of radiopharmaceutical dosages. A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains a photon-emitting radionuclide;

b. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements;

c. Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

d. Retain a record of the assays required by 41.2(19) “a” for three years. To satisfy this requirement, the record shall contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient’s or human research subject’s name and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

- (4) Date and time of the assay and administration; and
- (5) Initials of the individual who performed the assay.

41.2(20) *Authorization for calibration and reference sources.* Any person authorized by 41.2(3) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the U.S. Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed 30 millicuries (1.11 GBq) each;
- b. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq);
- c. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
- d. Technetium-99m amounts as needed.

41.2(21) *Requirements for possession of sealed sources and brachytherapy sources.*

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

- (1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and
- (2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21) “b,” the licensee shall ensure that:

- (1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;
- (2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
- (3) Test samples are taken when the source is in the “off” position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, the signature of the radiation safety officer and the signature of the individual performing the leak test.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

- (1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and
- (2) File a report with the agency within five days of receiving the leak test results. The report shall describe the equipment involved, the model and serial number of the leaking source, the radionuclide and its estimated activity, the test results, the date of the test, and the action taken.

f. A licensee need not perform a leak test on the following sources:

- (1) Sources containing only radioactive material with a half-life of less than 30 days;
- (2) Sources containing only radioactive material as a gas;
- (3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]
- (4) Seeds of iridium-192 encased in nylon ribbon; and
- (5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at 6-month intervals. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, the signature of the radiation safety officer and the signature of the individual performing the physical inventory.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21) "h" for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) Syringe shields.

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) Syringe labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) Vial shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) Vial shield labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) Surveys for contamination and ambient radiation dose rate.

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26) "a" and "b" so as to be able to measure dose rates as low as 0.1 millirem (1 μ Sv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26) "a" and "b" and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26) "e" so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26) "e" and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26) "a," "b," and "e" for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the

instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

i. A licensee does not need to perform the surveys required in this subrule in an area where the patient or human research subject is confined and cannot be released under 41.2(27).

41.2(27) Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

a. The licensee may authorize the release from its control of any individual who has been administered unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast feeding, and
- (2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

- (1) Using the retained activity rather than the activity administered,
- (2) Using an occupancy factor less than 0.25 at 1 meter,
- (3) Using the biological or effective half-life, or
- (4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) Mobile nuclear medicine service technical requirements. A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17) "b"(1) "d" and "e" and 41.2(18) "d" and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28) "e" for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) *Storage of volatiles and gases.*

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) *Decay-in-storage.*

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

- (1) Holds radioactive material for decay a minimum of ten half-lives;
- (2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
- (3) Removes or obliterates all radiation labels; and
- (4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30) "*a*," the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) *Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) "*j*" or equivalent NRC or agreement state requirements or from a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) "*h*" or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

- (1) An authorized nuclear pharmacist;
- (2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or
- (3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(31) "*b*"(1) or the physician who is an authorized user in 41.2(31) "*b*"(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(32) *Possession of survey instrument.* A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 μ Sv) per hour to 50 millirems (500 μ Sv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(33) *Use of unsealed by-product material for imaging and localization studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed by-product material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) "*j*" or equivalent NRC or agreement state requirements or a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) "*h*" or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

- (1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69);

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(33) “b”(1) or the physician who is an authorized user in 41.2(33) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(34) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

a. A licensee shall not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(2) More than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

b. A licensee preparing:

(1) Technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract; or

(2) Rubidium-82 radiopharmaceuticals from strontium-82/rubidium-82 generators shall measure the strontium-82 and strontium-85 concentration before the first patient use of the day.

c. A licensee who must measure molybdenum-99, strontium-82, or strontium-85 concentration shall retain a record of each measurement for three years. The record shall include:

(1) For each elution or extraction of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

(2) For each elution or extraction of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (kilobecquerels of strontium-82 per megabecquerel of rubidium-82), microcuries of strontium-85 per millicurie of rubidium-82 (kilobecquerels of strontium-85 per millicurie of rubidium-82), the date of the test, and the initials of the individual who performed the test.

d. A licensee shall report immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 41.2(34) “a”(1) and strontium-82 or strontium-85 concentration exceeding the limits specified in 41.2(34) “a”(2).

41.2(35) Control of aerosols and gases.

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35) “a” at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)“d” shall be recorded and retained for the duration of the license.

41.2(36) Possession of survey instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(37) Use of unsealed by-product material for which a written directive is required. A licensee may use any unsealed by-product material prepared for medical use and for which a written directive is required that:

a. Is obtained from:

(1) A manufacturer or preparer licensed under 641—paragraph 39.4(29)“j” or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641—paragraph 39.4(24)“h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69);

or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(37)“b”(1) or the physician who is an authorized user in 41.2(37)“b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

41.2(38) Safety instruction.

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(38)“a,” the instruction shall describe the licensee’s procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer, radiation safety officer designee, or authorized user in case of the patient’s or human research subject’s death or medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) and adopted by reference and included herein.

c. A licensee shall keep a record of individuals receiving instruction required by 41.2(38)“a,” a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) Safety precautions.

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

(1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under 41.2(27);

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) Possession of survey instruments. A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(41) Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

41.2(42) Availability of survey instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(43) Use of sources for brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

a. As approved in the Sealed Source and Device Registry; or

b. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(44) Safety instruction.

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(44) "a," the instruction shall describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient or human research subject control;

(4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26(136C) and visitation authorized in accordance with 641—40.26(136C);

(5) Procedures for notification of the radiation safety officer, radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(44) “a,” a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

41.2(45) Safety precautions.

a. For each patient or human research subject receiving implant therapy a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;

(2) Post the patient’s or human research subject’s door with a “Caution: Radioactive Materials” sign and note on the door or the patient’s or human research subject’s chart where and how long visitors may stay in the patient’s or human research subject’s room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant; and

(6) Have applicable emergency response equipment available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following removal of the source applicators.

b. A licensee shall notify the radiation safety officer, radiation safety officer designee, or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) Brachytherapy sources inventory.

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient’s or human research subject’s name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient’s or human research subject’s name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46) “b” and “c” for three years.

e. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

41.2(47) *Release of patients or human research subjects treated with temporary implants.*

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed and, for remote afterloaders, returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47) "a" for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) *Possession of survey instruments.* A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.* A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses as approved in the Sealed Source and Device Registry or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(50) *Installation, maintenance, adjustment, and repair.*

a. Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), or reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:

- a. Making any change in the treatment room shielding;
- b. Making any change in the location of the teletherapy unit within the treatment room;
- c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- d. Relocating the teletherapy unit; or
- e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

41.2(52) *Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*

a. A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by 41.2(52)“a”(4) must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 41.2(52)“a”(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

d. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual’s assigned duties, in:

(1) The procedures identified in 41.2(52)“a”(4); and

(2) The operating procedures for the unit.

e. The licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

f. A licensee shall retain a record for three years of individuals receiving instruction required by 41.2(52)“d,” a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. A copy of the procedures required in 41.2(52)“a”(4) and 41.2(52)“d”(2) shall be retained for three years.

41.2(53) *Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation “on” unless each treatment room entrance door is closed;

(2) Turn the beam of radiation “off” immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned “on” following an interlock interruption until all treatment room entrance doors are closed and the beam “on-off” control is reset at the console.

c. A licensee shall require any individual entering the treatment room to ensure, through the use of appropriate monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose-rate remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient's or human research subject's body, the licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in 41.2(53) "a" through "e," a licensee shall:

(1) For medium-dose-rate and pulsed-dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation of and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who have been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

(2) For high-dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this subparagraph, "physically present" means to be within hearing distance of normal voice.

(4) Notify the radiation safety officer, or the radiation safety officer designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

41.2(54) Possession of survey instrument. A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(55) Radiation monitoring device.

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55) "d" for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55) "e."

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) Viewing system. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) Dosimetry equipment.

a. Except for low-dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system has not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57) "a." This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 41.2(57) "a."

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57) "a" and "b," the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) Full calibration measurements on teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. *Teletherapy units.*

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements for each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:
 - Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;
 - Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding one year.

(2) To satisfy the requirements of 41.2(58) "a"(1), full calibration measurements must include determination of:

1. The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy and linearity over the range of use;
5. On-off error; and
6. The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58) "a"(2)"1" may be made using the dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58) "a" in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58) "a"(2)"1" for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent of all other radionuclides.

(6) Full calibration measurements required by 41.2(58) "a"(1) and physical decay corrections required in 41.2(58) "a"(5) must be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the unit and the source; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the measured timer accuracy for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements for each unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:
 - Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one quarter of a year for high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding one year for low-dose-rate remote afterloader units.

(2) To satisfy the requirements of 41.2(58) "b"(1), full calibration measurements must include, as applicable, determination of:

1. The output within ± 5 percent;
2. Source positioning accuracy to within ± 1 millimeter;
3. Source retraction with backup battery upon power failure;
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output.

(4) A licensee shall make full calibration measurements required by 41.2(58) "b"(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low-dose-rate remote afterloader units in 41.2(58) "b"(2), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one quarter of a year.

(6) For low-dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 41.2(58) "b."

(7) A licensee shall mathematically correct the outputs determined in 41.2(58) "b"(2)"1" for physical decay intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by 41.2(58)“b”(1) and physical decay corrections required by 41.2(58)“b”(7) must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of 41.2(58)“c”(1), full calibration measurements must include determination of:

1. The output within ± 3 percent;

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitches;

9. Emergency timing circuits; and

10. Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)“c”(2)“1” may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)“c”(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)“c”(2)“1” at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by 41.2(58)“c”(1) and physical decay corrections required in 41.2(58)“c”(5) must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

41.2(59) Periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. Teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy and timer linearity over the range of use;

2. On-off error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57); and

6. The difference between the measurement made in 41.2(59)“a”(1)“5” and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by 41.2(59)“a”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the result of each spot check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to ensure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the spot checks required in 41.2(59)“a”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)“a.” The record must include:

1. The date of the spot check;
2. The manufacturer’s name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required by 41.2(59)“a”(2) until the licensee no longer possesses the teletherapy unit.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

1. Before the first use of a high-dose-rate, medium-dose-rate, or pulsed-dose-rate remote afterloader unit on a given day;
2. Before each patient treatment with a low-dose-rate remote afterloader unit; and
3. After each source installation.

(2) A licensee shall perform the measurements required by 41.2(59)“b”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(4) To satisfy the requirements of 41.2(59)“b”(1), spot checks must, at a minimum, ensure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

(5) If the results of the spot checks required in 41.2(59)“b”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)“b”(4). The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required in 41.2(59)“b”(2) until the licensee no longer possesses the remote afterloader unit.

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks for the gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

(2) A licensee shall:

1. Perform the measurements required by 41.2(59)“c”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

2. Have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(3) To satisfy the requirements of 41.2(59)“c”(1)“1,” spot checks must, at a minimum:

1. Ensure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits; and stereotactic frames and localizing devices (trunnions).

2. Determine:

• The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);

- The difference between the measurement made in the above bulleted point and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

- Source output against computer calculation;
- Timer accuracy and linearity over the range of use;
- On-off error; and
- Trunnion centricity.

(4) To satisfy the requirements of 41.2(59) “c”(1) “2” and “3,” spot checks must ensure proper functioning of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(5) A licensee shall arrange as soon as possible for the repair of any system identified in 41.2(59) “c”(3) that is not operating properly.

(6) If the results of the spot checks required in 41.2(59) “c”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain for three years a record of each spot check required by 41.2(59) “c”(3) and (4). The record must include:

1. The date of the spot check;
2. The manufacturer’s name, model number, and serial number for the gamma stereotactic radiosurgery unit and the survey instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, on-off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(8) A licensee shall retain a copy of the procedures required in 41.2(59) “c”(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

41.2(60) Radiation surveys for teletherapy facilities.

a. In addition to the survey requirements in 641—40.36(136C), a person licensed under 641—41.2(136C) shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required in 41.2(60) “a” at installation of a new source, and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer’s name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the

teletherapy source while in the “off” position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59) “g” for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61) “a” indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62) “a,” and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Five-year inspection.*

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the agency, an agreement state, or the U.S. Nuclear Regulatory Commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector’s name, the inspector’s license number, the date of inspection, the manufacturer’s name and model number and serial number for both the teletherapy unit and gamma stereotactic radiosurgery unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Training for radiation safety officer.* Except as provided in 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by this agency, NRC, or an agreement state and who meets the requirements in 41.2(65) “d” and “e.” (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.) To have its certification process recognized, a specialty board shall:

(1) Require all candidates for certification to:

1. Hold a bachelor’s or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) Require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two years of either full-time practical training or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68), 41.2(69), or 41.2(75); and

3. Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an agency, NRC, or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of radioactive material involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

6. Using emergency procedures to control radioactive material; and

7. Disposing of radioactive material; or

c. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state under 41.2(74) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as a radiation safety officer and who meets the requirements in 41.2(65) "d" and "e"; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

d. Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in 41.2(65) "e" and 41.2(65) "a"(1) "1" and "2" or 41.2(65) "a"(2) "1" and "2" or 41.2(65) "b"(1) or 41.2(65) "c"(1), and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

e. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee is seeking approval. This training requirement may be satisfied by completing

training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval.

41.2(66) *Training for experienced radiation safety officer.* Rescinded IAB 3/29/06, effective 5/3/06.

41.2(67) *Training for uptake, dilution, and excretion studies.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(31) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(67) “*c.*” (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 41.2(67) “*c*”(1)“1” and “2”; and

(2) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(68) or 41.2(69) or meets equivalent NRC or agreement state requirements; or

c. (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

• Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(67) “*a*”(1) or 41.2(67) “*c*”(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 41.2(31).

41.2(68) *Training for imaging and localization studies.* Except as provided in 41.2(75), the licensee shall require the authorized user of unsealed radioactive material for the uses authorized under 41.2(33) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(68) “*c.*” (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 41.2(68)“c”(1)“1” and “2”; and

(2) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68)“c”(1)“2,” seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

c. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use;
- Radiation biology, and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68); 41.2(68)“c”(1)“2,” seventh bulleted paragraph, and 41.2(69); 41.2(75); or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Administering dosages of radioactive drugs to patients or human research subjects; and

- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68)“c”(1)“2,” seventh bulleted paragraph; 41.2(75); or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(68)“a”(1) or 41.2(68)“c”(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33).

41.2(69) Training for use of unsealed by-product material for which a written directive is required. Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(37) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(69)“b”(1)“2,” seventh bulleted paragraph, and 41.2(69)“b”(2). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 41.2(69)“b”(1)“1” through 41.2(69)“b”(1)“2,” fifth bulleted paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of

Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

1. Classroom and laboratory training in the following areas:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity;
 - Chemistry of radioactive material for medical use; and
 - Radiation biology; and
2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“*b*” must also have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)“*b*”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Reserved.
- Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

– Oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required;

– Oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);

– Parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; or

– Parenteral administration of any other radionuclide for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69)“*a*”(1) and 41.2(69)“*b*”(1)“2,” seventh bulleted paragraph, or 41.2(69)“*b*”(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)“*b*” must have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)“*b*”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status.

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) or quantities greater than 33 millicuries (1.22 gigabecquerels), see 41.2(81) or 41.2(82).

41.2(70) Training for use of manual brachytherapy sources. Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 41.2(43) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state, and who meets the requirements in 41.2(70) “*b*”(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements at a medical institution, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;

- Using administrative controls to prevent a medical event involving the use of radioactive material; and

- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70) “*b*”(1)“2”; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(70) “*a*”(1) or 41.2(70) “*b*”(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 41.2(43).

41.2(71) Training for ophthalmic use of strontium-90. Except as provided in 41.2(75), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under 41.2(70) or equivalent NRC or agreement state requirements; or

b. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and
 4. Radiation biology; and
- (2) Has completed supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
1. Examination of each individual to be treated;
 2. Calculation of the dose to be administered;
 3. Administration of the dose; and
 4. Follow-up and review of each individual's case history; and
- (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), 41.2(71) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71) "b"(1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

41.2(72) Training for use of sealed sources for diagnosis. Except as provided in 41.2(75), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in 41.2(72) "b" and "c" and whose certification has been recognized by the agency, NRC, or an agreement state. (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

c. Has completed training in the use of the device for the uses requested.

41.2(73) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for a use authorized under 41.2(49) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state, and who meets the requirements in 41.2(73) "b"(3) and 41.2(73) "c." (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

b. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

1. 200 hours of classroom and laboratory training in the following areas:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity; and
 - Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements at a medical institution, involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;
- Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- Checking and using survey meters; and
- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)“b”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)“a”(1) or 41.2(73)“b”(1) and (2), and 41.2(73)“c,” and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

c. Has received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization.

41.2(74) Training for an authorized medical physicist. Except as provided in 41.2(75), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(74)“b”(2) and 41.2(74)“c.” (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of either full-time practical training or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70), 41.2(73), or 41.2(75); and

(3) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

b. (1) Holds a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one

year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;
2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74)“a”(1) and (2) and 41.2(74)“c” or 41.2(74)“b”(1) and 41.2(74)“c,” and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

c. Has training for the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist who is authorized for the type of use for which the individual is seeking authorization.

41.2(75) *Training for experienced radiation safety officer, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, authorized users and teletherapy or medical physicists.*

a. (1) An individual identified as a radiation safety officer, teletherapy or medical physicist, or nuclear pharmacist on an agency, NRC or agreement state license or a permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, does not need to comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).

(2) An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on the agency, NRC, or agreement state license or permit issued by the agency, NRC, or agreement state broad scope licensee or issued by master material license permit or issued by a master material license permittee of broad scope between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).

b. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before January 1, 2003, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material issued by the agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

c. Individuals who need not comply with training requirements as described in this subrule may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

41.2(76) *Physician training in a three-month program.* Rescinded IAB 8/1/07, effective 9/5/07.

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(78) and 41.2(81), 41.2(82), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(75), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements of 41.2(78) "b." (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4. Using administrative controls to avoid medical events in the administration of by-product material; and

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

c. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78) "a"(1), (2), and (3), or 41.2(78) "b"(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

41.2(79) *Training for experienced nuclear pharmacists.* Rescinded IAB 8/1/07, effective 9/5/07.

41.2(80) *Training for nuclear medicine technologists.* Rescinded IAB 4/2/03, effective 5/7/03.

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a

written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(81)“c”(1) and (2) and whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(81)“c”(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.); or

b. Is an authorized user under 41.2(69)“a” or “b” for uses in the oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or 41.2(82) or equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b,” 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81)“c”(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)“b” must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131.

41.2(82) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(82)“c”(1) and (2), and whose certification has been recognized by the agency, NRC, or agreement state, and who meets the requirements in 41.2(82)“c”(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC’s Web page.); or

b. Is an authorized user under 41.2(69)“a” or “b” for oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or meets equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b,” 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)“c”(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131.

41.2(83) Provisions for the protection of human research subjects.

a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal Policy; and

(2) Obtain “informed consent,” as defined and described in the Federal Policy, from the human research subjects.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and

receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

- (1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and
- (2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) *Calibration measurements of brachytherapy sources.*

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

- (1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);
- (2) Determined the source positioning accuracy within applicators; and
- (3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84) "a."

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84) "a"(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84) "a" for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

- (1) The date of the calibration;
- (2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
- (3) The source output or activity;
- (4) The source positioning accuracy within the applicators; and
- (5) The signature of the authorized medical physicist.

41.2(85) *Decay of strontium-90 sources for ophthalmic treatment.*

a. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84).

b. A licensee shall retain a record of the activity of each strontium-90 source in accordance with 41.2(84).

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

- a.* The source-specific input parameters required by the dose calculation algorithm;
- b.* The accuracy of dose, dwell time, and treatment time calculations at representative points;
- c.* The accuracy of isodose plots and graphic displays;
- d.* The accuracy of the software used to determine sealed source positions from radiographic images; and
- e.* The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of unsealed by-product material or any therapeutic dose of radiation from by-product material.

- (1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable.

(2) The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

b. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate setting per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, dose per fraction, number of fractions and total dose; or

(6) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radioisotope, number of sources, and source strengths and dose; and

2. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose);

(7) For therapeutic use of radiation machines, see 41.3(14).

c. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

d. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives.

e. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41.

f. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

g. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable.

(2) The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

h. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

41.2(88) Other medical uses of by-product material or radiation from by-product material. A licensee may use by-product material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C)(e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

41.2(89) Training for the parenteral administration of unsealed by-product material requiring a written directive. Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

a. Is an authorized user under 41.2(69) for parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required or equivalent NRC or agreement state requirements; or

b. Is an authorized user under 41.2(70) or 41.2(73) or equivalent NRC or agreement state requirements, and who meets the requirements in 41.2(89) “d”; or

c. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73) and who meets the requirements in 41.2(89) “d”; or

d. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements, in the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 41.2(69) must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89) “b” or “c,” and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed by-product material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69) must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.

[ARC 7983B, IAB 7/29/09, effective 9/2/09; ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—41.3(136C) Therapeutic use of radiation machines.**41.3(1) Scope and applicability.**

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

“Accessible surface” means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

“Added filtration” means any filtration which is in addition to the inherent filtration.

“Beam-limiting device” means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

“Beam-scattering foil” means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

“Bent beam linear accelerator” means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

“Contact therapy system” means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

“Dose monitor unit (DMU)” means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

“External beam radiation therapy” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“Field flattening filter” means a filter used to homogenize the absorbed dose rate over the radiation field.

“Filter” means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

“Gantry” means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

“Interruption of irradiation” means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

“Isocenter” means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

“Megavolt (MV) (mega electron volt (MeV))” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

“Monitor unit (MU).” See “Dose monitor unit.”

“Moving beam radiation therapy” means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

“Nominal treatment distance” means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

“Periodic quality assurance check” means a procedure which is performed to ensure that a previous calibration continues to be valid.

“Practical range of electrons” corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in “Clinical

Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Radiation field." See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapy physicist" means an individual qualified in accordance with 41.3(6).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of 41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

- (1) Radiology or therapeutic radiology by the American Board of Radiology; or
- (2) Radiation oncology by the American Osteopathic Board of Radiology; or
- (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5) "b" above, the classroom and laboratory training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of ionization radiation; and
- (4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4) "b" above, training shall be under the supervision of an authorized user and shall include:

- (1) Reviewing the full calibration measurements and periodic quality assurance checks;
- (2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

- (3) Using administrative controls to prevent misadministrations;
- (4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

- (5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

- (1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

- (2) Selecting proper dose and how it is to be administered;

- (3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

- (4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5) "b," the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

- a.* Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

- b.* Be certified by the American Board of Radiology in:

- (1) Therapeutic radiological physics; or

- (2) Roentgen-ray and gamma-ray physics; or

- (3) X-ray and radium physics; or

- (4) Radiological physics; or

- (5) Therapeutic medical physics; or

- c.* Be certified by the American Board of Medical Physics in radiation oncology physics; or

- d.* Be certified by the Canadian College of Physicists in Medicine; or

- e.* Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16) "a," 41.3(17) "c" and "d," and 41.3(18) "e" and "f" under the supervision of a radiation therapy physicist during the year of work experience.

- f.* Rescinded IAB 4/3/02, effective 5/8/02.

41.3(7) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 42. The permit holder shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions

required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

- a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;
- b. The visiting authorized user meets the requirements of 41.3(5); and
- c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency:

- a. Report of acceptance testing;
- b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 41.3(136C), as well as the name(s) of person(s) who performed such activities;
- c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;
- d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.
- e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Form of records. Rescinded IAB 4/5/00, effective 5/10/00.

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

- (2) Each administration is in accordance with the written directive;
- (3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:
 1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and
 2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;
- (4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
- (5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

1. The total dose delivered differs from the prescribed dose by 20 percent or more; or
2. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;
2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

- (1) The registrant's name;
- (2) The name of the prescribing physician;
- (3) A brief description of the event;
- (4) Why the event occurred;
- (5) The effect, if any, on the individual or individuals who received the misadministration;
- (6) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- (7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any

appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

- (1) The registrant's name and the names of the individuals involved;
- (2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;
- (3) A brief description of the event; why it occurred; and the effect, if any, on the individual;
- (4) The actions, if any, taken or planned to prevent recurrence; and
- (5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1) "a" and "b."

(2) In addition to the requirements of 41.3(16) "a"(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;
2. After making any change in the location of the therapeutic radiation machine within the treatment room;
3. After relocating the therapeutic radiation machine; or
4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16) "a"(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16) "a"(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.

b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16) "a" indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraphs 40.26(1) "a" and "b," before beginning the treatment program the registrant shall:

- (1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1) "a" and "b";

- (2) Perform the survey required by 41.3(16) "a" again; and

- (3) Include in the report required by 41.3(16) "d" the results of the initial survey, a description of the modification made to comply with 41.3(5) "b"(1), and the results of the second survey; or

- (4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1) "a" and "b."

c. Dosimetry equipment.

- (1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

- (2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16) "c"(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16) "c"(1).

- (3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16) "c"(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16) "a" and "b" to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) Therapeutic radiation machines of less than 500 kV.

a. Equipment requirements.

- (1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate

measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17) "a"(1)"1" and 41.3(17) "a"(1)"2" for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;
3. Means for indicating X-ray tube potential and current;
4. The means for terminating an exposure at any time;
5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X-ray tube:

1. It shall be possible to activate only one X-ray tube at any time;
2. There shall be an indication at the control panel identifying which X-ray tube is activated; and
3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;
2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
4. When any door referred to in 41.3(17)"b"(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
2. At intervals not exceeding one year; and
3. Before medical use under the following conditions:
 - Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 41.3(17)“c”(1):

- Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

- If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17)“b”(3).

- (2) To satisfy the requirement of 41.3(17)“c”(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, “Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV” (1981).

- (3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer’s name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

- d. Periodic quality assurance checks.

- (1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

- (2) To satisfy the requirement of 41.3(17)“d”(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17)“c”(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17)“c”(1), shall be stated.

- (3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

- (4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist’s quality assurance check procedures, the system shall be recalibrated as required in 41.3(17)“c”(1);

- (5) The registrant shall use the dosimetry system described in 41.3(16)“c”(2) to make the quality assurance check required in 41.3(17)“d”;

- (6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

- (7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

- (8) Notwithstanding the requirements of 41.3(17)“d”(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17)“d”(6) and (7) have been performed within the 30 days prior to administration;

- (9) To satisfy the requirement of 41.3(17)“d”(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. The “BEAM-ON” and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17) “d”(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the manufacturer’s name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17) “a”(9)“5”;

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 41.3(17) “c” and “d” have been met.

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18) “a”(1)“1,” the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18) “a”(1)“1” to “3” for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam-limiting devices.

1. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10-centimeter by 10-centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
- A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)“a”(9) relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

- Irradiation shall not be possible until a selection of a filter or a positive selection to use “no filter” has been made at the treatment control panel, either manually or automatically;
- An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use; and
- An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

- Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

- Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

- Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

- Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

- Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

- Maintain a reading until intentionally reset;

- Have only one scale and no electrical or mechanical scale multiplying factors;

- Utilize a design such that increasing dose is displayed by increasing numbers; and

- In the event of power failure, the beam monitoring information required in 41.3(18) "a"(6) "4" displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(7) Beam symmetry.

1. Bent-beam linear accelerators with beam-flattening filter(s) subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18) "a"(7) "1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

4. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18) "a"(6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a

value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18) “a”(7)“2” and “3” for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator’s position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of “BEAM-ON” and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;

- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;

- An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.

- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18) "a"(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or

- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 41.3(136C), the control panel shall also:

1. Be located outside the treatment room;
2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
3. Provide an indication of whether radiation is being produced; and
4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1)"a" and "b," interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18)"a"(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18)"e" and protection surveys required by 41.3(16)"a";
2. Supervision and review of dosimetry;
3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18)“f”(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18)“d” shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16)“a,” 41.3(18)“e,” and 41.3(18)“f” have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Acceptance testing, commissioning, and full calibration measurements.

(1) Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Acceptance testing and commissioning shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45, and the manufacturer’s contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41 and shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and

- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)“e”(1)“3.”

(2) The registrant shall use the dosimetry system described in 41.3(16)“c” to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)“*f*”(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)“*c*”(1) to make the periodic quality assurance checks required in 41.3(18)“*f*”(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)“*f*”(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week or at longer intervals as recommended by the manufacturer;

(7) To satisfy the requirement of 41.3(18)“*f*”(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the “BEAM-ON,” interrupt and termination switches;

3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(8) Rescinded IAB 4/11/07, effective 5/16/07.

(9) The registrant shall promptly repair any system identified in 41.3(18)“*f*”(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)“*f*”(1) and 41.3(18)“*f*”(7) for three years. The record shall include the date of the quality assurance check, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the manufacturer’s name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

41.3(20) Calibration of survey instruments.

a. The registrant shall ensure that the survey instruments used to show compliance with 645—41.3(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

b. To satisfy the requirements of 41.3(20), the registrant shall:

(1) Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

(3) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(4) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

c. The registrant shall retain a record of each calibration required in 41.3(20) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

d. The registrant may obtain the services of individuals licensed by this agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in 41.3(20) shall be maintained by the registrant.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—41.4(136C) Radiation safety requirements for analytical X-ray equipment. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

“*Accreditation body*” means an entity that has been approved by FDA to accredit mammography facilities.

“*Action limits*” or “*action levels*” means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

“*Adverse event*” means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;

2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

3. Use of personnel who do not meet the applicable requirements of this chapter.

“Air kerma” means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

“Annually” means within 10 to 14 months of previous occurrence.

“Artifact” means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

“Automatic exposure control systems” means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

“Average glandular dose” means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: “Dose.”

“Breast implant” means a prosthetic device implanted in the breast.

“Calendar quarter” means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

“Category 1” means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

“Certificate” means the certificate described in 41.6(2)“a”(2).

“Certification” means the process of approval of a facility by the FDA or this agency to provide mammography services.

“Clinical image” means a mammogram.

“Compression device” means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

“Computed radiography mammography” means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

“Consumer” means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

“Contact hour” means an hour of training received through direct instruction.

“Continuing education unit” or *“continuing education credit”* means one contact hour of training.

“Craniocaudal view” means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

“Dedicated mammography equipment” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“Direct detector technology” means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

“Direct instruction” means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

“Direct supervision” means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient’s records; or

2. During the performance of a mammography examination or survey of the facility’s equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

“Dose” means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

“Exposure” means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen= 2.58×10^{-4} Coulombs of charge per kilogram of air.

“Facility” means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

“FDA” means the Food and Drug Administration.

“First allowable time” means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The “first allowable time” may vary with the certifying body.

“Full field digital mammography” means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

“Grids” means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

“Image noise.” See “Radiographic noise.”

“Image receptor support device” means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

“Interpreting physician” means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)“a.”

“Kerma” means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

“Laterality” means the designation of either the right or left breast.

“Lead interpreting physician” means the interpreting physician assigned the general responsibility for ensuring that a facility’s quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

“Mammogram” means a radiographic image produced through mammography.

“Mammographic modality” means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

“Mammography” means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

“Mammography equipment evaluation” means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

“Mammography medical outcomes audit” means a systematic collection of mammography results and the comparison of those results with outcomes data.

“Mammography unit(s)” means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

“Mean optical density” means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

“Medical physicist” means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)“c.”

“Mediolateral view” means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

“MQSA” means the Mammography Quality Standards Act of 1992.

“Multi-reading” means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

“Oblique mediolateral view” means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

“Patient” means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

“Phantom” means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

“Phantom image” means a radiographic image of a phantom.

“Physical science” means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

“Positive mammogram” means a mammogram that has an overall assessment of findings that are either “suspicious” or “highly suggestive of malignancy.”

“Provisional certification” means the six-month certification time period in which a facility has to complete the accreditation/certification process.

“Qualified instructor” means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter

include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

"Quality control technologist" means an individual meeting the requirements of 41.6(5) "a"(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiographic equipment" means X-ray equipment used for the production of static X-ray images.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3) "b."

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Reinstatement" means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

"Screen-film mammography" means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

"Supplier" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

"Survey" means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

41.6(2) Registration and application standards and requirements.

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency approval by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for one 90-day extension.

c. Suspension, revocation, or denial of mammography certification.

(1) Mammography certification may be suspended or revoked with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial, suspension or revocation of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order suspending or revoking certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is revoked, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions must be submitted with the application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A full certificate shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

f. The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:

(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and

3. Each mammography examination must have been interpreted as a “negative” or “benign” examination.

(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)“f”(1).

(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.

(4) Be billed the fee for the quality review process as set forth in 641—subparagraph 38.8(1)“b”(2).

(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)“f”(3).

g. Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.

h. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

i. Soft copy review workstation requirements.

(1) Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two monitors that meet one of the following criteria:

1. Have 5 megapixel resolution; or

2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer’s quality control manual or that outlined by the image receptor manufacturer’s designated soft copy review workstation quality control manual.

41.6(3) Mammography personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. *Interpreting physicians.* All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)“a”(3)“1” applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;

2. Either:

- Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

- Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)“a”; and

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution;

4. Unless the exemption in 41.6(3)“a”(3)“2” applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality or at least 8 hours of training in the new mammographic modality provided by a vendor manufacturing the new mammographic modality equipment. An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)“a”(2)“2” even if the course is taught multiple times during the previous 36 months.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)“a” or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)“a.” They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)“a”(1)“1” and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)“a”(1)“4.”

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)“a”(2)“1” shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

- Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician’s total to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)“a”(4)“1” shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information.

Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)“a”(2)“2” shall obtain a sufficient number of additional Category 1 continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)“b” before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)“b”; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)“b”(2)“3,” the technologist shall have at least 8 hours of continuing education units in the new modality. The 8 hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)“b”(3)“1” even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)“b”(3)“1” shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)“c”(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and

2. Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;

3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:

- A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics.

- Forty contact hours of documented specialized training in conducting surveys of mammography facilities.

- Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

- At least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date on which the requirements of 41.6(3)“c”(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date on which the requirements of this subrule were completed, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days shall be counted towards this requirement.

3. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.

(4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. *Retention of personnel records.* Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) Obtaining and preserving records.

a. The facility performing the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from other facilities, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

- (1) The date the mammography procedure was performed.
- (2) The date of the interpretation.
- (3) The name of the interpreting physician.
- (4) The name of the patient and an additional patient identifier.
- (5) A description of the procedures performed.
- (6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Assessment" with the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

6. "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service, as long as the patient continues consecutive mammograms. If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the retention period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4) "e"(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4) "b," to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) *Quality assurance program.*

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its

elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5) "e" through "k."

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

- (1) Conducting or training others to conduct equipment performance monitoring functions.

- (2) Analyzing the monitoring results to determine if there are any problems requiring correction.

- (3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

- (1) When the equipment is first installed.

- (2) After any major changes or replacement of parts.

- (3) At least annually during use based on recommendations of the mammography imaging medical physicist.

- (4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored for film-screen mammography shall include but not be limited to:

- (1) Processor performance (through daily sensitometric-densitometric means).

- (2) Half-value layer.

- (3) Output reproducibility and linearity.

- (4) Automatic exposure control reproducibility and linearity.

- (5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

- (6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

- (7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

- (1) Processor performance shall be accomplished daily before processing patient films.
- (2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.
- (3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results. Full field digital mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5)“k.” If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

h. Retake analysis program—film-screen and full field digital.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting

physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be below plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.
3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.
4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.
 - The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6

centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

- The optical density of the film in the center of the phantom image shall not be less than 1.20.
- 2. kVp accuracy and reproducibility.
 - The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.
 - At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.
- 3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.
 - Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
 - The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.
 - When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.
 - When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.
 - Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.
 - Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

- 4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.

- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5) “k”(5)“6.”

(7) Use of test results.

1. After completion of the tests specified in 41.6(5) “k,” the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer’s recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5) “k.”

3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer’s quality control manual or in accordance with the appropriate FDA-approved alternative requirements.

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5) “k”(5) and (6), the weekly phantom image quality test described in 41.6(5) “k”(2) and the quarterly retake analysis results described in 41.6(5) “h.”

2. The results of all tests conducted by the facility in accordance with 41.6(5) “k”(1) through (7) for film-screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer’s quality control manual. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and
 2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or
 3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.
 - l. Mammography procedures and techniques for mammography of patients with breast implants.
 - (1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.
 - (2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.
 - m. Consumer complaint mechanism. Each facility shall:
 - (1) Establish a written and documented system for collecting and resolving consumer complaints;
 - (2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;
 - (3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.
 - (4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.
 - n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.
 - o. Additional mammography review and patient notification.
 - (1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.
 - (2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.
- 41.6(6) Equipment standards.** The equipment used to perform mammography shall meet the following standards:
- a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.
 - b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.
 - c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.
 - (1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.
 - (2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.
 - (3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6) "i"(6) and (7).

(4) Except as provided in 41.6(6) "i"(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

- k.* AEC: Shall have automatic exposure control such that:
 - (1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.
 - (2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.
 - The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
 - The selected position of the detector shall be clearly indicated.
 - (3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.
 - l.* Control panel: Shall have a control panel that:
 - (1) Gives a positive indication when X-rays are being produced.
 - (2) Gives an audible signal indicating termination of exposure.
 - (3) Has manual selection of milliamperere seconds (mAs) or at least one of its component parts (milliamperere (mA) or time, or both).
 - (4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.
 - (5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.
 - m.* mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.
 - n.* Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.
 - o.* X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.
 - p.* Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.
 - q.* Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.
 - r.* Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.
 - s.* Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.
 - t.* Mobile units and vans—film-screen.
 - (1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.
 - (2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.
 - u.* Mobile units and vans—full field digital. Appropriate manufacturer's quality control manual procedures and criteria shall be met.
- 41.6(7) *Safety standards for mammography equipment.***
- a.* Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

- b. Equipment operators shall be monitored in accordance with 641—40.37(136C).
- c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.
- d. Equipment shall be shockproof and grounded to protect against electrical hazards.
- e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

RULE 641—41.6(136C)—APPENDIX I
Rescinded IAB 4/5/00, effective 5/10/00

RULE 641—41.6(136C)—APPENDIX II
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

Mo/Mo Target Filter X-Ray Voltage (kVp)												W/AI Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of $(0.50 \text{ R}) \times (174 \text{ mrad/R}) = 87 \text{ mrad}$ or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical

Physics Publishing; 159-175, 1991. W/AI conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.
[ARC 1401C, IAB 4/2/14, effective 5/7/14]

641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.

41.7(1) Definitions. In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

“Collaborative setting” means a setting in which a qualified radiologist and surgeon (under 41.7(3) “a” or 41.7(3) “c”) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient’s benefit.

“Procedure” means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

“Qualified training physician” means a physician who is qualified under 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

“Stereotactically guided breast biopsy” means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

“Supervising physician” means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) Registration and application standards and requirements.

a. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Suspension, revocation, or denial of authorization.

(1) Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial, suspension, or revocation of authorization.

(3) An emergency order suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is revoked, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A full reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

41.7(3) Physicians. Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3) “a.”

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in 41.7(3) “a”(1)“2” above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

5. Shall be responsible for the supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year. If experience is not maintained, the physician must requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic biopsy procedures according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.

5. Shall be responsible for supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3) "a."

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3) "c") performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.

2. Must have evaluated at least 480 mammograms in the prior 24 months in consultation with a physician who is qualified according to 41.6(3) "a."

3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3) "a."

2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

41.7(4) Medical physicist.

a. Must be qualified according to 41.6(3) "c."

b. Must have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4) "a" and 41.7(4) "b."

c. Maintenance of proficiency and continuing education requirements.

(1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and

(2) Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months.

41.7(5) Radiologic technologist.

a. Must be qualified according to 41.6(3) "b."

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641—41.7(136C).

(2) Three hours of continuing education in stereotactically guided breast biopsy. The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.

c. Maintenance of proficiency and continuing education and experience requirements.

(1) Following the first anniversary in which the requirements of this subrule were met, have performed at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5).

(2) Following the third anniversary in which the requirements of this subrule were met, have at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3) "b"(4) "1."

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

41.7(6) Obtaining and preserving records.

a. The facility must make, for each procedure, a record of the service provided including:

(1) The date of the procedure.

(2) The name of the patient and one additional patient identifier.

(3) The name of the radiologic technologists and physicians performing the procedure.

(4) A description of the service provided.

(5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

- (1) Quality assurance activities including the medical audit,
- (2) Oversight of the quality control program, and
- (3) Supervision of the radiologic technologist(s) and the medical physicist.

d. Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

- Digital – X-ray field must not extend beyond the image receptor by more than 5 mm on any side.

- Film-screen – On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.

- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

- Digital – Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.

- Film-screen – Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

- Digital – Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

- Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.

- Failures must be corrected before further procedures are performed.

9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.

10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test "lesion" in the sample chamber. Failures must be corrected before further procedures are performed.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

e. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.

(2) Visual checklist (monthly). Any failed items must be corrected within 30 days.

(3) Phantom image (weekly). Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures must be corrected before further procedures are performed.

(4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.

(5) Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer must be completed as outlined in the quality control manual applicable to the unit.

f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.

g. Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of a medical physicist qualified under 41.7(4).

41.7(8) *Equipment standards.*

a. Be specifically designed for stereotactically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

[ARC 1401C, IAB 4/2/14, effective 5/7/14]

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING
REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN
OPERATOR'S BOOTH1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m²).

(2) Regardless of size or shape, at least 0.09 m² (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS
PROPOSING TO CONDUCT HEALING
ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A detailed description of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the X-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the X-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.

16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.

17. The dates of the screening to include beginning and ending dates.

18. A copy of IRB for a research project or information justifying the research project.

CHAPTER 41—APPENDIX D

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance ^a
Daily	<u>Dosimetry</u>	
	X-ray output constancy	3%
	Electron output constancy ^b	3%
	<u>Mechanical</u>	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	<u>Safety</u>	
Monthly	Door interlocks	functional
	Audiovisual monitors	functional
	<u>Dosimetry</u>	
	X-ray output constancy ^c	2%
	Electron output constancy ^c	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	<u>Safety Interlocks</u>	
	Wedge, electron cone interlocks	functional
	<u>Mechanical</u>	
	Light/radiation field coincidence	2mm or 1% on a side ^d
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
Annual	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry ^e	2mm
	Field Light intensity	functional
	<u>Dosimetry</u>	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%

^a The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values \pm the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

^b All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

^c A constancy check with a field instrument using temperature pressure corrections.

^d Whichever is greater. Should also be checked after change of light field source.

^e Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance ^a
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy ^f	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	<u>Safety Interlocks</u>	
	Follow manufacturer's test procedures	functional
	<u>Mechanical</u>	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

^f Most wedges' transmission factors are field size and depth dependent.

^a The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values \pm the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

CHAPTER 41—APPENDIX E

INFORMATION ON RADIATION SHIELDING REQUIRED
FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and “allowed” radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, “Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV” (1976).

B. NCRP Report 51, “Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities” (1977).

C. NCRP Report 79, “Neutron Contamination from Medical Electron Accelerator” (1984).

D. NCRP Report 144, “Radiation Protection for Particle Accelerator Facilities” (2003).

These rules are intended to implement Iowa Code chapter 136C.

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[◇] Two or more ARCs

CHAPTER 45
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL
RADIOGRAPHIC OPERATIONS

[Prior to 8/5/92, see 641—41.4(136C)]

641—45.1(136C) General requirements for industrial radiography operations.

45.1(1) Purpose and scope.

a. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of November 5, 2014.

45.1(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapter 38 may also apply. As used in this chapter, the following definitions apply:

“Annual refresher safety training” means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

“Associated equipment” means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, e.g., guide tube, control tube, control (drive) cable, removable source stop, “J” tube and collimator when it is used as an exposure head.

“Cabinet X-ray system” means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet X-ray system is intended to:

1. Contain at least that portion of a material being irradiated;
2. Provide radiation attenuation; and
3. Exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

“Certifiable cabinet X-ray system” means an existing uncertified X-ray system that has been modified to meet certification requirements specified in 21 CFR 1020.40.

“Certified cabinet X-ray system” means an X-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

“Certifying entity” means an independent certifying organization meeting the requirements of Appendix A in 10 CFR Part 34 or an agreement state meeting the requirements in Appendix A, Parts II and III of 10 CFR Part 34.

“Collimator” means a small radiation shield of lead or other heavy metal that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

“Control (drive) cable” means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

“Control drive mechanism” means a device that enables the source assembly to be moved to and from the exposure device.

“Control tube” means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

“Crank-out device” means the cable, protective sheath, and handcrank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

“Enclosed radiography” means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded-room radiography.

“Exposure head” means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

“Field station” means a facility where licensed material may be stored or used and from which equipment is dispatched.

“Fluoroscopic imaging assembly” means a subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

“GED” means general educational development.

“Guide tube (projection sheath)” means a flexible or rigid tube (i.e., “J” tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

“Hands-on experience” means experience in all of those areas considered to be directly involved in the radiography process.

“I.D. card” means the document issued by the agency, another agreement state, a licensing state, or third-party certification to industrial radiographers following completion of requirements stated in 45.1(10)“b.”

“Independent certifying organization” means an independent organization that meets all of the criteria of Appendix A in 10 CFR Part 34.

“Lay-barge radiography” means industrial radiography performed on any water vessel used for laying pipe.

“Lixiscope” means a portable light-intensified imaging device using a sealed source.

“Lock-out survey” means a radiation survey performed to verify that a sealed source is in its shielded position. The lock-out survey is performed before moving the radiographic exposure device or source changer to a new location or when securing the radiographic exposure device or source changer.

“Minimal threat” means that during the operations of electronic devices capable of generating or emitting fields of radiation:

1. No deliberate exposure of an individual occurs;
2. The radiation is not emitted in an open beam configuration; and
3. No known physical injury to an individual has occurred.

“Offshore” means within the territorial waters of the United States.

“Offshore platform radiography” means industrial radiography conducted from an offshore platform over a body of water.

“Permanent radiographic installation” means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

“Practical examination” means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

“Radiation safety officer” means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of 45.1(10)“d.”

“Radiographer” means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)“b,” who performs or personally supervises industrial radiographic operations, and is responsible to the licensee or registrant for ensuring compliance with the requirement of these rules and all license and certificate of registration conditions.

“Radiographer certification” means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

“Radiographer’s assistant” means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10) “a” and who uses sources of radiation and related handling tools or radiation survey instruments under the direct supervision of a radiographer trainer.

“Radiographer trainer (instructor)” means any individual who instructs and supervises radiographer’s assistants during on-the-job training and who meets the requirements of 45.1(10) “c.”

“Radiographic exposure device” means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera), or any other X-ray industrial system whereby a permanent or semipermanent image is recorded on an image receptor by action of ionizing radiation.

“Radiographic operations” means all activities associated with the presence of radioactive sources or radiation in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

“Radiographic personnel” means any radiographer or radiographer’s assistant.

“Residential location” means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

“Shielded position” means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

“Shielded-room radiography” means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

“Source assembly” means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

“Source changer” means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

“Source container” means a shielded device in which sealed sources are secured, transported, and stored.

“Storage area” means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

“Storage container” means a shielded device in which sealed sources are secured, transported, and stored.

“S-tube” means a tube through which the radioactive source travels when inside a radiographic exposure device.

“Temporary job site” means any location where radiographic operations are conducted and where licensed material may be stored other than the location(s) listed in a specific license or certificate of registration.

“Trainee status card” means the document issued by the agency following completion of the requirements of 45.1(10) “a”(1) and (2).

“Transport container” means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

“Underwater radiography” means industrial radiography performed when the radiographic exposure device and related equipment are beneath the surface of the water.

45.1(3) Exemptions.

a. Uses of certified and certifiable cabinet X-ray systems designed to exclude individuals are exempt from the requirements of this chapter, except for the requirements of 45.2(6) “b” and “c.”

b. Industrial uses of lixiscopes are exempt from the requirements in this chapter.

c. Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with 641—subrule 38.3(1) are exempt from the rules in this chapter, except for the requirements of this subrule.

45.1(4) *Receipt, transfer, and disposal of sources of radiation.* Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation. These records shall include the date, the name of the individual making the record, the radionuclide, number of curies or mass (for DU), and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for three years after they are made.

45.1(5) *Radiation survey instruments.*

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make physical radiation surveys as required by this chapter and 641—subrule 40.36(1). Instrumentation required by this subrule shall have a range such that 2 millirems (0.02 millisievert) per hour through 1 rem (0.01 sievert) per hour can be measured.

b. Notwithstanding the requirements of 641—subrule 40.36(3) each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed six months and after each instrument servicing;

(2) Such that accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked;

(3) At 2 points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at 3 points between 2 and 1000 mrem per hour for digital instruments; and

(4) By a person licensed or registered by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission to perform such service.

c. Records of these calibrations shall be maintained for three years after the calibration date for inspection by the agency.

d. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

45.1(6) *Quarterly inventory.* Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed. Sources of radiation include radiographic exposure devices containing depleted uranium. The records of the inventories shall be maintained for three years from the date of the inventory for inspection by the agency and shall include: the manufacturer, model number, serial number, radionuclide, number of curies, and location of each source of radiation; number of kilograms of depleted uranium shielding; date of the inventory; and name of the individual making the inventory.

45.1(7) *Utilization logs.*

a. Each licensee shall maintain utilization logs of the use of each sealed source. The logs shall include:

(1) A unique description, which includes the make, model, and serial number of each radiographic exposure device containing a sealed source or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom the sealed source is assigned;

(3) The plant or site where each sealed source is used and the date of use; and

(4) The date(s) each sealed source is removed from storage and returned to storage.

b. Each registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(1) A unique identification, which includes the make, model and serial number of each source of radiation;

(2) The identity of the radiographer using the source of radiation;

(3) The date(s) each source of radiation is energized or used and the number of exposures made.

c. Utilization logs may be kept on clear, legible records containing all the information required by 45.1(7) “a” or “b.” Copies of utilization logs shall be maintained for agency inspection for three years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

45.1(8) *Inspection and maintenance.*

a. Each licensee or registrant shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means.

b. Each licensee or registrant shall have written procedures and conduct a program, at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, source changers, survey instruments, and associated equipment to ensure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer’s specifications. Replacement components shall meet design specifications. This program shall cover, as a minimum, the items in Appendix B of this chapter.

c. Each licensee shall have a program and written procedures for the inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The program must include procedures to ensure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

d. If equipment problems are found, the equipment must be removed from service until repaired.

e. The record of equipment problems and of any maintenance performed under 45.1(8) must be retained for three years after the record is made. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair or maintenance, if any, was performed.

45.1(9) *Permanent radiographic installations.* Permanent radiographic installations having high radiation area entrance controls of the type described in 641—paragraphs 40.42(1) “b” and “c” shall also meet the following requirements:

a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the agency for three years from the date of the event.

45.1(10) *Training and testing for radiographic personnel.*

a. Radiographer’s assistant requirements. No licensee or registrant shall permit any individual to act as a radiographer’s assistant, as defined in this chapter, until:

(1) It has been documented on the appropriate agency form or equivalent that such individual has received copies of and has demonstrated an understanding of:

1. The subjects outlined in Appendix A, presented in a 40-hour course approved by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission;

2. The rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40;

3. The appropriate conditions of license(s) or certificate(s) of registration;

4. The licensee’s or registrant’s operating and emergency procedures;

5. And developed competence to use, under the personal supervision of the radiographer, the licensee’s or registrant’s radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use;

6. And has demonstrated competence in the use of radiographic exposure devices, sources, survey instruments and associated equipment described in 45.1(10)“a”(1) by successful completion of a practical examination covering this material.

(2) The individual possesses a current agency-issued trainee status card issued after completion of 45.1(10)“a”(1). Trainee status will be granted only once for each individual and is valid for no longer than two years.

b. Radiographer requirements. No licensee or registrant shall permit any individual to act as a radiographer:

(1) Until it has been documented to the agency that such individual:

1. Has completed the requirements of 45.1(10)“a”(1);

2. Has completed on-the-job training as a radiographic trainee supervised by one or more radiographic trainers. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines, or both. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (three months or 480 hours). Active participation does not include safety meetings or classroom training;

3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments by successful completion of a practical examination covering this material;

(2) Unless the individual has successfully completed within the last five years the appropriate agency-administered examination prescribed in 45.1(10)“f”(2) or equivalent examination; and

(3) Unless the individual possesses a current I.D. card.

c. Radiographer trainer. No individual shall act as a radiographer trainer unless such individual:

(1) Has met the requirements of 45.1(10)“a”(1) and “b”;

(2) Has one year of documented experience as an industrial radiographer and possesses a current ID card issued at least one year prior to the application for a trainer card; and

(3) Is named on the specific license or certificate of registration issued by the agency and under which an individual is acting as a radiographer trainer, or

(4) Possesses a valid radiographer trainer card issued by the agency.

d. Radiation safety officer. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee’s program.

(1) A radiation safety officer (RSO) shall be designated for every industrial radiography license and certificate of registration issued by the agency.

(2) The RSO’s qualifications shall include:

1. Possession of a high school diploma or a certificate of high school equivalency based on the GED test;

2. Completion of the training and testing requirements of 45.1(10)“a”(1) and 45.1(10)“b”(1)“3,” (2), and (3);

3. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

4. Formal training in the establishment and maintenance of a radiation protection program.

The agency will consider alternatives when the RSO has either appropriate training or experience, or both, in the field of ionizing radiation and, in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(3) The specific duties of the RSO include, but are not limited to, the following:

1. To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

2. To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

3. To ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

4. To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

5. To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

6. To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

7. To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

8. To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

9. To maintain records as required by these rules (see Appendix C);

10. To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

11. To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.2(3), and 45.3(6) “b”; and

12. To ensure that personnel are complying with these rules, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant.

e. Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10) “a” and “b” are met for all industrial radiographic personnel. Records shall be maintained until disposal is authorized by the agency. The agency shall not release records for disposal unless the records have been maintained at least three years.

f. Applications and examinations.

(1) Application.

1. An application for taking the examination shall be on forms prescribed and furnished by the agency along with the fee required in 641—subrule 38.8(3). The application shall be submitted only after the training requirements of 45.1(10) “a” and “b” have been completed.

2. An individual whose I.D. card has been suspended or revoked shall obtain prior approval from the agency to apply to take the examination.

(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

1. A written examination shall be held at such times and places as the agency shall determine. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will emphasize the applicant’s ability to safely use sources of radiation and related equipment and the applicant’s knowledge of these rules.

2. A candidate failing an examination may apply for reexamination in accordance with 45.1(10) “f”(1) and will be reexamined. A candidate shall not retake the same version of the agency-administered examination.

3. The examination will be held at locations designated by the agency. The examination shall normally be offered quarterly. Dates, times, and locations of the examinations will be provided by the agency.

4. The examination will be in the English language.

5. To take the examination, an individual shall have a picture identification card (such as an Iowa driver’s license) at the time of the examination.

6. Calculators will be permitted during the examination; however, calculators or computers with preprogrammed data or formulas, including exposure calculations, will not be permitted.

7. The examination will be a “closed book” examination.

8. Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to the administration is prohibited.

9. Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual may resubmit an application and an additional examination fee to take the examination not earlier than three months later.

10. The names and scores of individuals taking the examination shall be a public record.

g. Identification procedures.

(1) I.D. card.

1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10) "b" and the examination prescribed in 45.1(10) "f"(2) or an equivalent examination.

2. Each person's I.D. card shall contain the person's photograph.

3. The I.D. card remains the property of the state of Iowa and may be revoked or suspended under the provisions of 45.1(10) "h."

4. Any individual who wishes to replace the I.D. card shall submit to the agency a written request for a replacement I.D. card, stating the reason a replacement I.D. card is needed and the fee required in 641—subrule 38.8(3). The individual shall maintain in possession a copy of the request while performing industrial radiographic operations until a replacement I.D. card is received from the agency.

(2) Expiration of I.D. card. Each I.D. card expires at the end of the day, in the month and year stated on the I.D. card.

(3) Renewal of I.D. card.

1. Applications for examination to renew an I.D. card shall be filed in accordance with 45.1(10) "f"(1).

2. The examination for renewal of an I.D. card shall be administered in accordance with 45.1(10) "f"(2).

3. A renewed I.D. card shall be issued in accordance with 45.1(10) "g"(1).

h. Revocation or suspension of an I.D. card.

(1) Any radiographer who violates these rules may be required to show cause at a formal hearing why the I.D. card should not be revoked or suspended.

(2) When an agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending the I.D. card, the industrial radiographer shall surrender the I.D. card to the agency until such time as the order is changed or the suspension expires.

(3) An agency's inspector may, in certain instances, confiscate any radiographer's I.D. card on the spot while conducting an inspection or investigation. If the inspector determines that the activities being conducted by the radiographer are significant enough to be classified as severity I, II, or III, as specified in 641—38.5(136C), and after obtaining the approval of agency management, the inspector may take any radiographer's I.D. card. The agency will then issue a cease and desist order to the radiographer's employer, forward the I.D. card(s) to the issuing entity, and notify the U.S. Nuclear Regulatory Commission and other agreement states.

i. Exemptions. Any person using a source of radiation to determine the presence of explosives in a package or the authenticity of a piece of art is exempt from the provisions of 45.1(10) "a" to "h."

j. Reciprocity.

(1) Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category and class issued by a certifying entity as defined in 45.1(2).

2. The requirements and procedures of the certifying entity issuing the certification require the same or comparable certification standards as those required by 45.1(10) "a" through "e"; and

3. The individual submits a legible copy of the certification to the agency prior to entry into Iowa.

(2) Enforcement actions with the agency, another agreement state, or the U.S. Nuclear Regulatory Commission or any sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(3) Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 45.1(10) “b.”

45.1(11) *Internal audits.* Except as provided in 45.1(11) “c,” the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer’s assistant to ensure that these rules, license requirements, and the licensee’s or registrant’s operating and emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and radiographer’s assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

b. Provide that, if a radiographer or radiographer’s assistant has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or radiographer’s assistant must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before the individual can next participate in a radiographic operation.

c. The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

d. Records of audits shall be maintained by the licensee or registrant for agency inspection for three years from the date of the audit.

45.1(12) *Personnel monitoring control.*

a. The personnel monitoring program shall meet the applicable requirements of 641—Chapter 40.

b. When performing industrial radiographic operations:

(1) No licensee or registrant shall permit an individual to act as a radiographer, radiographer’s assistant, or radiographer trainer unless at all times during radiographic operations each individual wears, on the trunk of the body, a combination of direct-reading pocket dosimeter, an operating alarm ratemeter, and a film badge, an optically stimulated luminescent device (OSL device) or a thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.

(2) Pocket dosimeters or electronic personal dosimeters shall meet the criteria in ANSI N322-1977 and shall have a range of zero to at least 200 millirems. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(3) Pocket dosimeters or electronic personal dosimeters shall be recharged at the start of each work shift.

(4) Pocket dosimeters or electronic personal dosimeters shall be read and exposures recorded at the beginning and at the end of each work shift, and before each recharging.

(5) If an individual’s pocket dosimeter is discharged beyond its range (i.e., goes “off scale”), or if the electronic personal dosimeter reads greater than 200 millirem (2 millisievert), and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual shall cease and the individual’s film badge, OSL device, or TLD shall be within 24 hours sent for processing. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination must be made by the RSO or the RSO’s designee. The results of this determination must be included in the exposure records maintained in accordance with 641—Chapter 40.

(6) Each individual monitoring device shall be assigned to and worn by only one individual.

(7) Film badges, OSL devices and TLDs must be replaced at least monthly.

(8) If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated

exposure and the time period for which the individual monitoring device was lost or damaged must be included in the records maintained in 45.1(12)“c.”

c. Records of pocket dosimeter readings of personnel exposures and yearly operability checks required in 45.1(12)“d” shall be maintained for three years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained for three years after they are recorded. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges, OSLs, or TLDs, shall be maintained until the agency terminates the license.

d. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the agency for three years from the date of the event.

e. Reports received from the film badge, OSL device or TLD processor shall be kept for inspection by the agency until the agency terminates the license.

f. Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift. Records of alarm function checks shall be maintained for two years by the licensee or registrant for agency inspection;

(2) Be set to give an alarm signal at a preset dose rate of 500 mR/hr;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of the alarming ratemeter calibrations shall be maintained for three years by the licensee or registrant for agency inspection.

45.1(13) *Supervision of radiographer's assistant.* Whenever a radiographer's assistant uses radiographic exposure devices, sealed sources or associated equipment or conducts radiation surveys required by 45.2(5) or 45.3(7) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the direct supervision of a radiographer instructor. The direct supervision must include:

a. The radiographer's physical presence at the site where the source(s) of radiation is being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the radiographer's assistant's performance of the operations referred to in this subrule.

45.1(14) *Access control.*

a. During each industrial radiographic operation, a radiographer or radiographer's assistant shall maintain continuous, direct visual surveillance of the operation to protect against unauthorized entry into a restricted area, radiation area or high radiation area, except at permanent radiographic installations where all entryways are locked to protect against unauthorized or accidental entry and the requirements of 45.1(9) are met.

b. Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.

45.1(15) *Posting.*

a. Notwithstanding any provisions in 641—subrule 40.62(1) areas in which radiography is being performed shall be conspicuously posted as required by 641—subrules 40.61(1) and 40.61(2).

b. Whenever practicable, ropes or barriers shall be used in addition to appropriate signs to designate areas in accordance with 641—subrule 40.26(1) and to help prevent unauthorized entry.

c. During pipeline industrial radiography operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the radiation area.

d. Notwithstanding the requirements of 45.1(15)“a,” a restricted area may be established in accordance with 641—subrule 40.26(1) and may be posted in accordance with 40.61(1) and 40.61(2), i.e., both signs may be posted at the same location at the boundary of the restricted area.

45.1(16) Temporary job site requirements.

a. Documents and records. Each licensee or registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the agency:

- (1) Appropriate license or certificate of registration or equivalent document;
- (2) The appropriate operating and emergency procedures;
- (3) The applicable agency rules;
- (4) Survey records required pursuant to 45.2(5) “d” and 45.3(7) “j” for the period of operation at the site;
- (5) Daily pocket dosimeter records for the period of operation at the site;
- (6) The daily alarming ratemeter records for the period of operation at the site; and
- (7) The latest radiation survey instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter and decay charts for sources which have been manufactured within the last six months.

b. Reserved.

45.1(17) Specific requirements for radiographic personnel performing industrial radiography.

a. At a job site, the following shall be supplied by the licensee or registrant:

- (1) At least one operable, calibrated radiation survey instrument;
- (2) A current whole body personnel monitor (TLD, OSL device or film badge) for each individual;
- (3) An operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens (5.16×10^{-5} C/kg) for each worker; and
- (4) An operable, calibrated alarm ratemeter for each worker; and
- (5) The appropriate barrier ropes and signs.

b. Each radiographer at a job site shall possess a valid I.D. card.

c. Each radiographer’s assistant at a job site shall possess a valid trainee status card issued by the agency.

d. Industrial radiographic operations shall not be performed if any of the items in 45.1(17) “a,” “b,” and “c” are not available at the job site or are inoperable.

e. No individual other than a radiographer or a radiographer’s assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

f. During an inspection by the agency, the agency inspector may terminate an operation if any of the items in 45.1(17) “a” are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

45.1(18) Notification of incidents.

a. The agency shall be notified of thefts or losses of sources of radiation, overexposures, and excessive levels in accordance with 641—40.95(136C) and 40.97(136C).

b. Each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:

- (1) The source assembly cannot be returned to the fully shielded position and properly secured;
- (2) The source assembly becomes disconnected from the drive cable;
- (3) The failure of any component (critical to safe operation of the radiographic exposure device) to properly perform its intended function; or
- (4) An indicator on a radiation-producing machine fails to show that radiation is being produced or an exposure switch fails to terminate production of radiation when turned to the off position.

c. The licensee or registrant shall include the following information in each report submitted in accordance with 45.1(18) “b”:

- (1) A description of the equipment problem;
- (2) Cause of each incident, if known;
- (3) Manufacturer and model number of equipment involved in the incident;
- (4) Location, time, and date of the incident;
- (5) Actions taken to establish normal operations;
- (6) Corrective actions taken or planned to prevent recurrence; and

(7) Names of personnel involved in the incident.

45.1(19) *Copies of operating and emergency procedures.* Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the agency terminates the license. Superseded material must be retained for three years after the change is made.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—45.2(136C) Radiation safety requirements for the use of radiation machines in industrial radiography.

45.2(1) *Locking of sources of radiation.* The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an X-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer.

45.2(2) *Permanent storage precautions.* Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

45.2(3) *Requirements for radiation machines used in industrial radiographic operations.*

a. Equipment used in industrial radiographic operations involving radiation machines manufactured after January 1, 1992, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537-1976.

b. The registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on all vehicles used to transport radiation machines for temporary job site use.

45.2(4) *Operating and emergency procedures.*

a. The registrant's operating and emergency procedures shall include instructions in at least the following:

- (1) Operation and safety instruction on the radiation machine(s) to be used;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
- (6) Minimizing exposure of individuals in the event of an accident;
- (7) The procedure for notifying proper personnel in the event of an accident;
- (8) Maintenance of records; and
- (9) Inspection and maintenance of radiation machines.

b. Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a radiographer's assistant, the other shall be a radiographer trainer authorized by the certificate of registration.

c. No individual other than a radiographer or a radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

d. Rescinded IAB 4/8/98, effective 7/1/98.

45.2(5) *Radiation surveys and survey records.*

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and used at each site where radiographic exposures are made.

b. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

c. All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 45.1(15), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm

that 45.1(15) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

d. Records shall be kept of the surveys required by 45.2(5) “*b*” and “*c*.” Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual’s exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.2(6) *Special requirements and exemptions for enclosed radiography.*

a. Systems for enclosed radiography, including shielded-room radiography and cabinet radiography, designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this chapter and 641—subrule 40.26(1). If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of three years after the evaluation.

b. Certified and certifiable cabinet X-ray systems are exempt from the requirements of this chapter except that:

(1) Operating personnel must be provided with individual monitoring devices in accordance with the appropriate provisions of 641—40.37(136C).

(2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the agency until disposition is authorized by the agency.

(3) Tests for proper operation of interlocks used to control entry to the high radiation area or alarm systems, where applicable, shall be conducted and recorded every three months. Records of these tests shall be maintained for agency inspection until disposal is authorized by the agency.

(4) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with 641—subrule 40.26(1). If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the agency pursuant to 641—38.3(136C).

45.2(7) *Registration for industrial radiographic operations.*

a. Radiation machines used in industrial radiographic operations shall be registered in accordance with 641—Chapter 39.

b. In addition to the registration requirements in 641—Chapter 39, an application for a certificate of registration shall include the following information:

(1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,
2. Periodic training,
3. On-the-job training, and

4. Methods to be used by the registrant to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, registration requirements, and the operating and emergency procedures of the applicant.

(2) Written operating and emergency procedures, including all items listed in Appendix D.

(3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow registration provisions, rules of the agency, and the applicant’s operating and emergency procedures.

(4) A list of permanent radiographic installations and descriptions of permanent storage and use locations.

(5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.

c. A certificate of registration will be issued if the requirements of 641—Chapter 39 and this subrule are met.

641—45.3(136C) Radiation safety requirements for use of sealed sources of radiation in industrial radiography.

45.3(1) *Limits on external radiation levels from storage containers and source changers.* The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisievert) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

45.3(2) *Locking of sources of radiation.*

a. Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental removal of the sealed source. Either the exposure device or its container must be kept locked and, if applicable, the key removed, at all times when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 45.1(14). Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if the lock is a keyed lock, with the key removed at all times) when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to ensure that the sealed source is in the shielded position.

c. The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 45.3(7) "b."

45.3(3) *Storage precautions.*

a. Labeling, storage, and transportation.

(1) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording: "CAUTION RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or name of company)," or "DANGER."

(2) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 641—39.5(136C).

(3) Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(4) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

b. Radiographic exposure devices, source changers, or storage containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with 45.3(3) "c," and if the vehicle does not constitute a permanent storage location as described in 45.1(9).

c. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

- (1) Telephone service is established by the licensee;
- (2) Industrial radiographic services are advertised for or from the location;
- (3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

45.3(4) *Performance requirements for radiography equipment.* Equipment used in industrial radiographic operations must meet the following minimum criteria:

a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036, telephone (212)642-4900.

b. In addition to the requirements specified in paragraph "a" of this subrule, the following requirements apply to radiographic exposure devices, source changers, source assemblies, sealed sources, and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and the date on which this activity was last measured;
3. Model number (or product code) and serial number of the sealed source;
4. Manufacturer's identity of the sealed source; and
5. Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 641—39.5(136C).

(3) Modification of any radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in paragraphs "a" and "b" of this subrule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operation or source changing:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter;

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with safe operation of the exposure device or associated equipment;

(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;

(6) Guide tubes must be used when moving the source out of the device;

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations;

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980;

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

d. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, must comply with the requirements of this subrule.

e. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this subrule.

f. Notwithstanding the requirements of 45.3(4) “*a*,” equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

g. Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component pursuant to the above-referenced standard.

45.3(5) *Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.*

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state.

b. Leak testing requirements.

(1) Each licensee that uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by this agency. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by this agency to perform the analysis.

(2) The licensee shall maintain records of the leak tests results for sealed sources and devices containing depleted uranium (DU). The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

c. Any test conducted under this subrule which reveals the presence of 0.005 microcuries (185 Bq) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw from use the equipment involved and shall have it decontaminated and repaired or disposed of in accordance with agency rules. Within five days after obtaining the results of the test, the licensee shall file a report with the agency describing the equipment involved, the test results, and the corrective action taken.

d. Each exposure device using DU shielding and an “S” tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency to perform the analysis. Should such testing reveal the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure

device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU-shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for DU contamination if the interval of storage exceeds 12 months.

e. Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: "Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities if Found."

45.3(6) *Operating and emergency procedures.*

a. The licensee's operating and emergency procedures shall include instructions in at least the following:

- (1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in 641—Chapter 40;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
- (6) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;
- (7) Minimizing exposure of individuals in the event of an accident;
- (8) The procedure for notifying proper personnel in the event of an accident;
- (9) Maintenance of records;
- (10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines;
- (11) The procedure(s) for identifying and reporting defects and noncompliance in 10 CFR Part 21; and
- (12) Source recovery procedure if the licensee will perform source recovery.

b. Rescinded IAB 4/8/98, effective 7/1/98.

c. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or a radiographer's assistant. If one of the personnel is a radiographer's assistant, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography shall not be performed if only one qualified individual is present.

d. Collimators shall be used in industrial radiographic operations which use crank-out devices except when physically impossible.

e. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the agency.

45.3(7) *Radiation surveys and survey records.*

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and for each exposure device used at each site where radiographic exposures are made.

b. A survey with a calibrated and operable radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube and collimator. The survey required by this subrule must be done before exchanging films, repositioning the exposure head or dismantling the equipment.

c. (1) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 641—40.61(136C), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure

(i.e., with the sealed source in the exposed position) to confirm that 641—40.61(136C) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

(2) Each time the exposure device is relocated or the exposed position of the sealed source is changed, the requirements of 45.3(7) “c”(1) shall be met.

(3) The requirements of 45.3(7) “c”(2) do not apply to pipeline industrial radiographic operations when the conditions of exposure include, but are not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.

d. A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be made to determine that each sealed source is in its shielded position before securing the radiographic exposure device or source changer.

e. The sealed source shall be secured in its shielded position by locking the radiographic exposure device or source changer each time the sealed source is returned to its shielded position.

f. Each radiographic exposure device and source changer shall be locked and the key removed from any keyed lock prior to being moved or transported from one location to another and also prior to being stored at a given location.

g. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

h. Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 641—40.15(136C). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

i. A survey meeting the requirements of 45.3(7) “b” shall be performed on the radiographic exposure device and the source changer after every sealed source exchange. A survey shall be made of the storage area as defined in 641—45.2(136C) whenever a radiographic exposure device is being placed in storage.

j. Records shall be kept of the surveys required by 45.3(7) “c,” “d,” “g,” “h,” and “i.” Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual’s exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.3(8) Requirements for enclosed radiography.

a. Systems for enclosed radiography, including shielded-room radiography designed to allow admittance of individuals shall comply with all applicable requirements of this chapter.

b. Procedures shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with 45.1(9) “b.”

45.3(9) Underwater, offshore platform, and lay-barge radiography.

a. Underwater, offshore platform, or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 641—paragraph 39.4(27) “e.”

b. In addition to the other rules of this chapter, the following rules apply to the performance of lay-barge or offshore platform radiography:

(1) Cobalt-60 sources with activities in excess of 20 curies (nominal) and iridium-192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of lay-barge or offshore platform industrial radiography.

(2) Collimators shall be used for all industrial radiographic operations performed on lay-barge or offshore platforms.

45.3(10) Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

45.3(11) Licensing for industrial radiographic operations. Rescinded IAB 4/5/00, effective 5/10/00. [ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—45.4(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.

45.4(1) Purpose and scope.

a. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C).

c. The requirements of 45.1(10)“*b*”(2) and (3) and 45.1(10)“*d*”(1)“2” do not apply to nonradiographic uses.

45.4(2) Definitions. For purposes of this subrule, definitions in 641—Chapters 38 and 40 and subrule 45.1(2) may also apply. As used in this rule, the following definitions apply:

“*Cold pasteurization*” means the process of using radiation for destroying disease-causing microorganisms in commercial products.

“*Self-shielded particle accelerator*” means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self-shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self-shielded particle accelerator.

“*Shielded facility*” means an accelerator facility where shielding is required to be constructed on site in order to assure compliance with the requirements of 641—Chapter 40, or where shielding supplied with the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

45.4(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration or license issued pursuant to 641—39.1(136C) to 39.4(136C) and the following requirements:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

b. For accelerator facilities required to be licensed in accordance with 45.4(3), those operations that would require personnel monitoring, pursuant to 641—40.37(136C), due to the presence of radioactive material, shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance as well as routine operations.

45.4(4) General requirements for the issuance of a registration or license for particle accelerators. Along with the requirements of 641—39.1(136C) to 39.4(136C), an application for use of a particle accelerator will be approved only if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this rule and 641—Chapter 40 in such a manner as to minimize danger to public health and safety or property;

- b.* The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;
- c.* The issuance of the registration or license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 45.4(4);
- d.* The applicant has appointed a radiation safety officer responsible for the day-to-day operation of the radiation safety program;
- e.* The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;
- f.* The applicant has an adequate training program for operators of particle accelerators.

45.4(5) *Personnel monitoring.* In addition to the requirements of 641—Chapter 40, personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are required unless a survey of the area has determined that radiation levels are below that of a high radiation area; and

- a.* Power to an accelerator cannot be activated; or
- b.* An accelerated beam cannot be directed to the area.

45.4(6) *Operations.*

a. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

- (1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;
- (2) Has received copies of and instruction in this rule and the applicable requirements of 641—Chapter 40, pertinent registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and
- (3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

b. The radiation safety officer or radiation safety committee, if applicable, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

c. Along with the audit required in 641—subrule 40.10(3), each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed six months. If an operator has not participated in an accelerator operation for more than six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation. Records of the audits shall be maintained by the registrant for the agency inspection for three years from the date of the audit.

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of 45.1(10).

45.4(7) *Shielding and safety design requirements.*

a. A qualified expert acceptable to the agency shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

b. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

c. In addition to the requirements of 45.4(8) "a" and "b," shielded facilities or self-shielded particle accelerators shall meet the following requirements:

- (1) Authorization, by issuance of a construction permit, shall be granted upon a determination of adequacy being made pursuant to the review of an initial application of the shielding design, physical plant, and site specifications, and of the applicant's proposed equipment, uses and workloads. For a shielded facility, the applicant shall submit an evaluation of the shielding design by a qualified expert. For a self-shielded particle accelerator, the applicant need not submit an evaluation of a shielding design if an evaluation by an appropriate regulatory authority has been performed. The applicant may instead reference this evaluation. The applicant shall maintain a copy of the evaluation of shielding design for agency review.

(2) Authorization for installation and testing of an accelerator shall be given only after a determination of adequacy of testing protocols, testing safety procedures, staff training, and radiation detection instrumentation has been made; and

(3) Operational use of an accelerator shall be authorized only after determination of adequacy of the items listed in 45.4(4) has been made by the agency.

45.4(8) Particle accelerator controls and interlock systems.

a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, easily discernible and located outside the high radiation area.

b. Each entrance into a target area or other high radiation area shall be provided with two safety interlocks that shut down the machine when the barrier is breached.

c. Each safety interlock shall be on a circuit that allows it to operate independently of all other safety interlocks.

d. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

e. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

45.4(9) Warning devices.

a. Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

b. Each high radiation area shall have an audible warning device that shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—40.61(136C).

45.4(10) Operating and emergency procedures.

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency for three years.

d. All incidents in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or, if applicable, the radiation safety committee. Documentation shall be maintained for inspection by the agency for three years.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety officer and, if applicable, the radiation safety committee;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

f. The registrant's operating and emergency procedures shall include the following:

(1) Operation and safety instructions on the accelerator(s) to be used;

(2) Methods for controlling access to restricted areas;

(3) Methods and occasions for locking and securing sources of radiation;

(4) Use of personnel monitoring equipment;

(5) The procedure for notifying proper personnel in the event of an accident;

(6) Maintenance of records;

- (7) Inspections and maintenance of the accelerator; and
- (8) Steps to be taken in the case of an emergency.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

45.4(11) Radiation monitoring requirements.

a. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

b. Accelerator facilities shall survey with a radiation detection instrument at intervals not to exceed 12 months. Records of this survey shall be maintained for agency review for three years.

c. Accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall survey for removable contamination at intervals not to exceed six months to determine the degree of contamination.

d. Each time removable shields on self-shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage. In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator. Records of this survey shall be maintained for agency review for three years.

e. Accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

f. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

g. Upon installation, all area monitoring equipment shall be tested to assure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

h. Whenever applicable, accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

i. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert who is acceptable to the agency.

j. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

45.4(12) Radiation safety officer.

a. Each registrant shall appoint a radiation safety officer that meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents two years of radiation protection experience.

b. The specific duties of the RSO include, but are not limited to, the following:

(1) To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

(2) To oversee and approve all phases of the training program for accelerator operators so that appropriate and effective radiation protection practices are taught;

(3) To ensure that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

(5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(6) To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

- (7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;
- (8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
- (9) To maintain records as required by these rules;
- (10) To ensure the proper storing, labeling, and use of the accelerator;
- (11) To ensure that inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.4(10) “c”; and
- (12) To ensure that personnel are complying with these rules and the operating and emergency procedures of the registrant.

641—45.5(136C) Radiation safety requirements for analytical X-ray equipment.

45.5(1) Purpose and scope. This rule provides special requirements for analytical X-ray equipment. The requirements of this rule are in addition to, and not in substitution for, 641—Chapters 38, 39, and 40. The requirements of rules 641—45.1(136C) to 641—45.4(136C) do not apply.

45.5(2) Definitions. For the purpose of this subrule, definitions in 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

“*Analytical X-ray equipment*” means equipment used for X-ray diffraction or fluorescence analysis.

“*Analytical X-ray system*” means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

“*Fail-safe characteristics*” means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

“*Local components*” means part of an analytical X-ray system and includes X-ray areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

“*Normal operating procedures*” means step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

“*Open-beam configuration*” means an analytical X-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

“*Primary beam*” means radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

45.5(3) Equipment requirements.

a. Safety device. A device which prevents the entry of any portion of an individual’s body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

- (1) A description of the various safety devices that have been evaluated;
- (2) The reason each of these devices cannot be used; and
- (3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

b. Warning devices.

- (1) Open-beam configurations shall be provided with a readily discernible indication of:
 1. X-ray tube “on-off” status located near the radiation source housing, if the primary beam is controlled in this manner; or
 2. Shutter “open-closed” status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
- (2) An easily visible warning light labeled with the words “X-RAY ON,” or words having a similar intent, shall be located:

1. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

2. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of these rules, warning devices shall have fail-safe characteristics.

c. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

d. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION—HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the X-ray source housing; and

(2) "CAUTION—RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

(3) "CAUTION—RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 641—40.63(136C) if the radiation source is a radionuclide.

e. Shutters. On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

(1) Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 mSv) in one hour.

45.5(4) Area requirements.

a. Radiation levels. The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 641—40.26(136C). For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

b. Surveys.

(1) Radiation surveys, as required by 641—40.36(136C), of all analytical X-ray systems sufficient to show compliance with 45.5(4) "a" shall be performed:

1. Upon installation of the equipment, and at least once every 12 months thereafter;

2. Following any change in the initial arrangement, number, or type of local components in the system;

3. Following any maintenance requiring the disassembly or removal of a local component in the system;

4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;

5. Anytime a visual inspection of the local components in the system reveals an abnormal condition; and

6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 641—40.15(136C).

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with 45.5(4) “a” to the satisfaction of the agency.

c. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words “CAUTION—X-RAY EQUIPMENT” or words having a similar intent in accordance with 641—subrule 40.61(1).

45.5(5) Operating requirements.

a. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

b. Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words “SAFETY DEVICE NOT WORKING,” or words having a similar intent, shall be placed on the radiation source housing.

c. Repair or modification of X-ray tube systems. Except as specified in 45.5(5) “b,” no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

d. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

45.5(6) Personnel requirements.

a. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to:

- (1) Identification of radiation hazards associated with the use of the equipment;
- (2) Significance of the various radiation warnings, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
- (3) Proper operating procedures for the equipment;
- (4) Recognition of symptoms of an acute localized exposure; and
- (5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

- (1) Finger or wrist dosimetry devices shall be provided to and shall be used by:
 1. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 2. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 40.2(1) unless evaluated by a qualified expert.

641—45.6(136C) Radiation safety requirements for well-logging, wireline service operations and subsurface tracer studies.

45.6(1) Purpose. This rule establishes radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this rule are in addition to, and not in substitution for, the requirements of 641—Chapters 38, 39, and 40. The requirements of 641—45.1(136C) to 641—45.5(136C) do not apply.

45.6(2) Scope. This rule applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.

45.6(3) Definitions. For the purpose of this subrule, the definitions of 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

“Energy compensation source (ECS)” means a small sealed source, with an activity not exceeding 3.7 MBq (100 microcuries), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool’s calibration when in use.

“Fresh water aquifer” means a geologic formation that is capable of yielding fresh water to a well or spring.

“Injection tool” means a device used for controlled subsurface injection of radioactive tracer material.

“Logging assistant” means any individual who, under the direct supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 45.6(22).

“Logging supervisor” means the individual who uses licensed material or provides direct supervision in the use of licensed material at a temporary job site and who is responsible to the licensee for ensuring compliance with the requirements of these rules and the conditions of the license.

“Logging tool” means a device used subsurface to perform well-logging.

“Personal supervision” means guidance and instruction by the logging supervisor who is physically present at the temporary job site, who is in personal contact with logging assistants, and who can give immediate assistance.

“Radioactive marker” means licensed material used for depth determination or direction orientation. For purposes of this rule, this term includes radioactive collar markers and radioactive iron nails.

“Safety review” means a periodic review on radiation safety aspects of well-logging provided by the licensee for its employees. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

“Source holder” means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well-logging operations.

“Subsurface tracer study” means the release of unsealed licensed material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

“Surface casing” for protecting fresh water aquifers means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

“Temporary job site” means a place where licensed materials are present for the purpose of performing well-logging or subsurface tracer studies.

“Tritium neutron generator target source” means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

“Uranium sinker bar” means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

“Well” means a drilled hole in which well-logging may be performed. As used in this rule, “well” includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

“Well-logging” means all operations involving the lowering and raising of measuring devices or tools which may contain licensed material or are used to detect licensed materials in wells for the purpose of obtaining information about the well or adjacent formations and which may be used in oil, gas, mineral, groundwater, or geological exploration.

“Wireline” means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

“Wireline service operation” means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

45.6(4) Agreement with well owner or operator.

a. A licensee may perform well-logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

- (1) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;
- (2) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;
- (3) The radiation monitoring required in 45.6(8) and 45.6(17) will be performed;
- (4) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and
- (5) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

1. Each irretrievable well-logging source must be immobilized and sealed in place with a cement plug;

2. There must be a means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

3. A permanent identification plaque, constructed of long-lasting material, such as stainless steel, brass, bronze, or Monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm (7 inches) square and 3 mm (1/8-inch) thick. The plaque must contain:

- The word "Caution";
- The radiation symbol (the color requirement in 641—40.60(136C) need not be met);
- The date the source was abandoned;
- The name of the well owner or well operator, as appropriate;
- The well name and well identification number(s) or other designation;
- An identification of the sealed source(s) by radionuclide and quantity;
- The depth of the source and depth to the top of the plug; and
- An appropriate warning such as, "Do not reenter this well."

- b. The licensee shall retain a copy of the written agreement for three years after the completion of the well-logging operation.

- c. A licensee may apply, pursuant to 641—38.3(136C), for agency approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well-logging source in a manner not otherwise authorized in 45.6(26) "a"(5).

- d. A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in 45.6(26) "a"(1) through (5).

45.6(5) *Limits on levels of radiation.* Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of 641—39.5(136C) and the dose limitation requirements of 641—Chapter 40 are met.

45.6(6) *Storage precautions.*

- a. Each source of radiation shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

- b. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

45.6(7) *Transport precautions.* Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

45.6(8) *Radiation survey instruments.*

- a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this subrule and by 641—40.36(136C). Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour.

- b. Each radiation survey instrument shall be calibrated:

- (1) At intervals not to exceed six months and after each instrument servicing;

(2) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(3) So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

c. Calibration records shall be maintained for a period of two years for inspection by the agency.

45.6(9) *Leak testing of sealed sources.*

a. *Testing and record-keeping requirements.* Each licensee using sealed sources of radioactive material shall have the sources tested for leakage periodically. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for three years after the leak test is performed.

b. *Method of testing.* Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the NRC, an agreement state, or a licensing state. The wipe of a sealed source must be performed using a leak test kit or method approved by the NRC, an agreement state, or a licensing state. The wipe sample must be taken from the nearest assessable point to the sealed source where contamination might accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

c. *Interval of testing.*

(1) Each sealed source of radioactive material (except an energy compensation source (ECS)) shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made six months prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(2) Each ECS that is not exempt from testing in accordance with 45.6(9) "c"(1) must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the ECS may not be used until tested.

d. *Leaking or contaminated sources.*

(1) If the test in 45.6(9) "c" reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of by an NRC, agreement state, or licensing state licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by an NRC, agreement state, or licensing state licensee that is authorized to perform these functions.

(2) A report describing the equipment involved, the test results, any contamination which resulted from the leaking source, and the corrective action taken up to the time of the report shall be filed with the agency within five days of receiving the test results.

e. *Exemptions.* The following sources are exempted from the periodic leak test requirements of 45.6(9) "a" to "d":

- (1) Hydrogen-3 (tritium) sources;
- (2) Sources of radioactive material with a half-life of 30 days or less;
- (3) Sealed sources of radioactive material in gaseous form;
- (4) Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and
- (5) Sources of alpha- or neutron-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

45.6(10) *Quarterly inventory.* Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

45.6(11) *Utilization records.* Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the agency for two years from the date of the recorded event, showing the following information for each source of radiation:

- a. Make, model number, and a serial number or a description of each source of radiation used;
- b. The identity of the well-logging supervisor or field unit to whom assigned;
- c. Locations where used and dates of use; and
- d. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

45.6(12) Design, performance, and certification criteria for sealed sources used in well-logging operations.

- a. A licensee may use a sealed source for use in well-logging applications if:
 - (1) The sealed source is doubly encapsulated construction;
 - (2) The sealed source contains chemical and physical forms that are as insoluble and nondispersible as practical; and
 - (3) The sealed source meets the requirements of 45.6(12) “b,” “c,” and “d.”
- b. For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source for use in well-logging applications if it meets the requirements of USASI N5.10-1968, “Classification of Sealed Radioactive Sources,” or the requirements in 45.6(12) “c” or “d.”
- c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for well-logging applications if it meets the oil-well-logging requirements of ANSI/HPS N43.6-1997, “Sealed Radioactive Sources—Classification.”
- d. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for use in well-logging applications if the sealed source’s prototype has been tested and found to maintain its integrity after each of the following tests.
 - (1) Temperature. The test source must be held at -40 degrees C for 20 minutes, 600 degrees C for one hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees C within 15 seconds.
 - (2) Impact test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.
 - (3) Vibration test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.
 - (4) Puncture test. A one gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.
 - (5) Pressure test. The test source must be subject to an external pressure of 1.695×10^7 pascals (24,600 pounds per square inch absolute).
- e. The requirements in 45.6(12) “a,” “b,” “c,” and “d” do not apply to sealed sources that contain licensed material in gaseous form.
- f. The requirements of 45.6(12) “a,” “b,” “c,” and “d” do not apply to energy compensation sources (ECS). ECSs must be registered with the NRC, licensing state, or agreement state.

45.6(13) Labeling.

- a. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER¹
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

- b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER¹
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES
[OR NAME OF COMPANY]

45.6(14) Inspection and maintenance.

- a. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers,

transport containers, and injection tools to ensure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the agency.

b. If any inspection conducted pursuant to 45.6(14) “a” reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

c. If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform this operation.

d. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

45.6(15) Training requirements.

a. No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this rule until such individual has:

(1) Received, in a course recognized by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, instruction in the subjects outlined in Appendix E of this chapter and demonstrated an understanding thereof;

(2) Read and received instruction in the rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee’s or registrant’s operating and emergency procedures, and demonstrated an understanding thereof; and

(3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

b. No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) Read or received instruction in the licensee’s or registrant’s operating and emergency procedures and demonstrated an understanding thereof; and

(2) Demonstrated competence to use, under the direct supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

c. The licensee or registrant shall maintain employee training records for inspection by the agency for two years following termination of the individual’s employment.

45.6(16) Operating and emergency procedures. Each licensee or registrant shall develop and follow written operating and emergency procedures that cover:

a. The handling and use of sources of radiation, including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

¹or CAUTION

b. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

c. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 45.6(22);

d. Minimizing personnel exposure, including exposures from inhalation and ingestion of licensed tracer materials;

e. Methods and occasions for locking and securing stored licensed or registered materials;

f. Personnel monitoring and the use of personnel monitoring equipment;

g. Transportation of licensed or registered materials to field stations or temporary job sites, packaging of licensed or registered materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;

h. Picking up, receiving, and opening packages containing licensed or registered materials, in accordance with 641—40.65(136C);

i. For the use of tracers, decontamination of the environment, equipment, and personnel;

- j. Maintenance of records generated by well logging personnel at temporary job sites;
- k. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 45.6(14);
- l. Identifying and reporting defects and noncompliance;
- m. Actions to be taken if a sealed source is lodged in a well;
- n. Notifying proper persons in the event of an accident; and
- o. Actions to be taken if a sealed source is ruptured that include actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required in 45.6(8).

45.6(17) *Personnel monitoring.*

- a. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears, at all times during the handling of licensed radioactive materials, a film badge, OSL device or thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). Each film badge, OSL device or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSL devices and TLDs replaced at least quarterly. After replacement, each film badge, OSL device or TLD must be promptly processed.
- b. The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.
- c. Personnel monitoring records and bioassay results shall be maintained for inspection until the agency authorizes disposition.

45.6(18) *Security.* During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in 641—Chapter 38.

45.6(19) *Handling tools.* The licensee shall provide and require the use of tools that will ensure remote handling of sealed sources other than low activity calibration sources.

45.6(20) *Subsurface tracer studies.*

- a. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.
- b. No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency and any other appropriate state agency.

45.6(21) *Particle accelerators.* No licensee or registrant shall permit aboveground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of 641—40.15(136C) and 641—40.26(136C), as applicable, are met.

45.6(22) *Radiation surveys.*

- a. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.
- b. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.
- c. If the sealed source assembly is removed from the logging tool before departing the job site, the logging tool detector shall be energized, or a survey meter used, to ensure that the logging tool is free of contamination.
- d. Radiation surveys shall be made and recorded at the job site or wellhead for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.
- e. Records required pursuant to 45.6(22)“a” to “d” shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description

of the location of the survey. Records of these surveys shall be maintained for inspection by the agency for two years after completion of the survey.

45.6(23) Documents and records required at field stations. Each licensee or registrant shall maintain, for inspection by the agency, the following documents and records for the specific devices and sources used at the field station:

- a. Appropriate license, certificate of registration, or equivalent document(s);
- b. Operating and emergency procedures;
- c. Applicable regulations;
- d. Records of the latest survey instrument calibrations pursuant to 45.6(8);
- e. Records of the latest leak test results pursuant to 45.6(9);
- f. Records of quarterly inventories required pursuant to 45.6(10);
- g. Utilization records required pursuant to 45.6(11);
- h. Records of inspection and maintenance required pursuant to 45.6(14);
- i. Survey records required pursuant to 45.6(22); and
- j. Training records required pursuant to 45.6(15).

45.6(24) Documents and records required at temporary job sites. Each licensee or registrant conducting operations at a temporary job site shall have the following documents and records available at that site for inspection by the agency:

- a. Operating and emergency procedures;
- b. Survey records required pursuant to 45.6(22) for the period of operation at the site;
- c. Evidence of current calibration for the radiation survey instruments in use at the site;
- d. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and
- e. Shipping papers for the transportation of radioactive material.

45.6(25) Notification of incidents, abandonment, and lost sources.

a. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of 641—Chapter 40.

b. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

(2) Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

c. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) Advise the well operator of the regulations of the appropriate state agency regarding abandonment and an appropriate method of abandonment, which shall include:

1. The immobilization and sealing in place of the radioactive source with a cement plug;
2. The setting of a whipstock or other deflection device; and
3. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by 45.6(25) “d.”

(2) Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures, or specify the implemented abandonment before receiving approval because the licensee believed there was an immediate threat to public health and safety; and

(3) File a written report with the agency within 30 days of the abandonment. The licensee shall send a copy of the report to the appropriate state agency that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:

1. Date of occurrence;

2. A description of the well-logging source involved, including the radionuclide and its quantity, chemical, and physical form;
 3. Surface location and identification of the well;
 4. Results of efforts to immobilize and seal the source in place;
 5. A brief description of the attempted recovery effort;
 6. Depth of the source;
 7. Depth of the top of the cement plug;
 8. Depth of the well;
 9. The immediate threat to public health and safety justification for implementing abandonment if prior approval was not obtained in accordance with 45.6(25) “c”(2);
 10. Any other information, such as a warning statement, contained on the permanent identification plaque; and
 11. The names of state agencies receiving a copy of this report.
- d.* Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque² for posting the well or well-bore. This plaque shall:
- (1) Be constructed of long-lasting material, such as stainless steel or Monel; and
 - (2) Contain the following information engraved on its face:
 1. The word “CAUTION”;
 2. The radiation symbol without the conventional color requirement;
 3. The date of abandonment;
 4. The name of the well operator or well owner;
 5. The well name and well identification number(s) or other designation;
 6. The sealed source(s) by radionuclide and activity;
 7. The source depth and the depth to the top of the plug; and
 8. An appropriate warning, depending on the specific circumstances of each abandonment.³
- e.* The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

45.6(26) Reserved.

45.6(27) *Radioactive markers.* The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the quantities specified in 641—Chapter 39, Appendix B, Exempt Quantities. The use of markers is subject only to the requirements of 45.6(10).

45.6(28) *Uranium sinker bars.* The licensee may use uranium sinker bars in well-logging applications only if they are legibly impressed with the words “CAUTION—RADIOACTIVE-DEPLETED URANIUM” and “NOTIFY CIVIL AUTHORITIES [or Company name] IF FOUND.”

45.6(29) *Use of a sealed source in a well without a surface casing.* The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source’s becoming lodged in the well. The procedure must be approved by the NRC or licensing or agreement state.

45.6(30) *Energy compensation source.* The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

a. For well-logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 45.6(9) to 45.6(11).

b. For well-logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 45.6(4), 45.6(9) to 45.6(11), 45.6(25), and 45.6(29).

45.6(31) *Tritium neutron generator target source.*

a. Use of a tritium neutron generator target source that contains quantities not exceeding 30 curies (1110 MBq) and that is in a well with a surface casing to protect fresh water aquifers is subject to the requirements of this rule except subrules 45.6(4), 45.6(12), and 45.6(25).

b. Use of a tritium neutron generator target source that contains quantities exceeding 30 curies (1110 MBq) or that is in a well without a surface casing to protect fresh water aquifers is subject to the requirements of this rule except subrule 45.6(12).

²An example of a suggested plaque is shown in Appendix F of this chapter.

³Appropriate warnings may include: (a) "Do not drill below plug-back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Iowa Department of Public Health."

CHAPTER 45—APPENDIX A

SUBJECTS FOR INSTRUCTION OF
RADIOGRAPHER'S ASSISTANTS

Training provided to qualify individuals as radiographer's assistants in compliance with 45.1(10) shall be presented on a formal basis. The training shall include the following subjects:

- I. Fundamentals of radiation safety
 - A. Characteristics of radiation
 - B. Units of radiation dose and quantity of radioactivity
 - C. Significance of radiation dose
 - 1. Radiation protection standards
 - 2. Biological effects of radiation
 - 3. Case histories of radiography accidents
 - D. Levels of radiation from sources of radiation
 - E. Methods of controlling radiation dose
 - 1. Working time
 - 2. Working distances
 - 3. Shielding
- II. Radiation detection instrumentation to be used
 - A. Use of radiation survey instruments
 - 1. Operation
 - 2. Calibration
 - 3. Limitations
 - B. Survey techniques
 - C. Use of personnel monitoring equipment
 - 1. Film badges
 - 2. Thermoluminescent dosimeters (TLDs)
 - 3. Pocket dosimeters
 - 4. OSL devices
- III. The requirements of pertinent federal and state regulations
- IV. The licensee's or registrant's written operating and emergency procedures
- V. Radiographic equipment to be used
 - A. Remote handling equipment
 - B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtailed)
 - C. Storage and transport containers, source changers
 - D. Operation and control of X-ray equipment
 - E. Collimators

CHAPTER 45—APPENDIX B

GENERAL REQUIREMENTS FOR INSPECTION OF
INDUSTRIAL RADIOGRAPHIC EQUIPMENT

- I. Panoramic devices (devices in which the sealed source is physically removed from the shielded container during exposure) shall be inspected for:
 - A. Radiographic exposure unit
 - 1. Abnormal surface radiation levels anywhere on camera, collimator, or guide tube;
 - 2. Condition of safety plugs;
 - 3. Proper operation of locking mechanism;
 - 4. Condition of pigtail connector;
 - 5. Condition of carrying device (straps, handle, etc.);
 - 6. Proper labeling.
 - B. Source tube
 - 1. Rust, dirt, or sludge buildup inside the source tube;
 - 2. Condition of source tube connector;
 - 3. Condition of source stop;
 - 4. Kinks or damage that could prevent proper operation;
 - 5. Presence of radioactive contamination.
 - C. Control cables and drive mechanism
 - 1. Proper drive mechanism with camera, as appropriate;
 - 2. Changes in general operating characteristics;
 - 3. Condition of connector on drive cable;
 - 4. Drive cable flexibility, wear, and rust;
 - 5. Excessive wear or damage to crank assembly parts;
 - 6. Damage to drive cable conduit that could prevent the cable from moving easily;
 - 7. Connection of the control cable connector with the pigtail connector for proper mating;
 - 8. Proper operation of source position indicator, if applicable;
 - 9. Presence of radioactive contamination.
- II. Directional beam devices shall be inspected for:
 - A. Abnormal surface radiation;
 - B. Changes in the general operating characteristics of the unit;
 - C. Proper operation of shutter mechanism;
 - D. Chafing or binding of shutter mechanism;
 - E. Damage to the device that might impair its operation;
 - F. Proper operation of locking mechanism;
 - G. Proper drive mechanism with camera, as appropriate;
 - H. Condition of carrying device (strap, handle, etc.);
 - I. Proper labeling.
- III. X-ray equipment shall be inspected for:
 - A. Change in the general operating characteristics of the unit;
 - B. Wear of electrical cables and connectors;
 - C. Proper labeling of console;
 - D. Proper console with machine, as appropriate;
 - E. Proper operation of locking mechanism;
 - F. Timer run-down cutoff;
 - G. Damage to tube head housing that might result in excessive radiation levels.

CHAPTER 45—APPENDIX C

TIME REQUIREMENTS FOR RECORD KEEPING

Specific Section	Name of Record	Time Interval Required for Record Keeping

45.1(4)	Receipt, transfer and disposal.	3 years.
45.1(5)	Survey instrument calibrations.	3 years.
45.1(6)	Quarterly inventory.	3 years.
45.1(7)	Utilization logs.	3 years.
45.1(8)	Quarterly inspection and maintenance.	3 years.
45.1(9)	High radiation area control devices or alarm systems.	Until disposal is authorized by the agency.
45.1(10)	Training and testing records.	3 years.
45.1(12)	Pocket dosimeter readings.	3 years.
	Pocket dosimeter calibrations.	3 years.
	Film badge, OSL device, or TLD reports.	Until the agency terminates the license.
	Alarming ratemeter calibrations.	3 years.
	Alarming ratemeter functions.	3 years.
	Estimates of overexposures.	Until the agency terminates the license.
45.1(19)	Current operating and emergency procedures.	Until the license is terminated.
	Superseded material.	3 years after change.
40.81(1)	Internal audit program.	3 years.
45.1(11)	Radiographer audits.	3 years.
45.2(5) and 45.3(7)	Radiation surveys.	2 years or until disposal is authorized by the agency if a survey was used to determine an individual's exposure.
45.1(16)	Records at temporary job sites.	During temporary job site operations.
45.2(6) and 45.3(8)	Annual evaluation of enclosed X-ray systems.	2 years.
45.3(5)	Leak tests.	3 years.
45.2(6)	Evaluation of certified cabinet X-ray systems.	2 years.

CHAPTER 45—APPENDIX D

OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

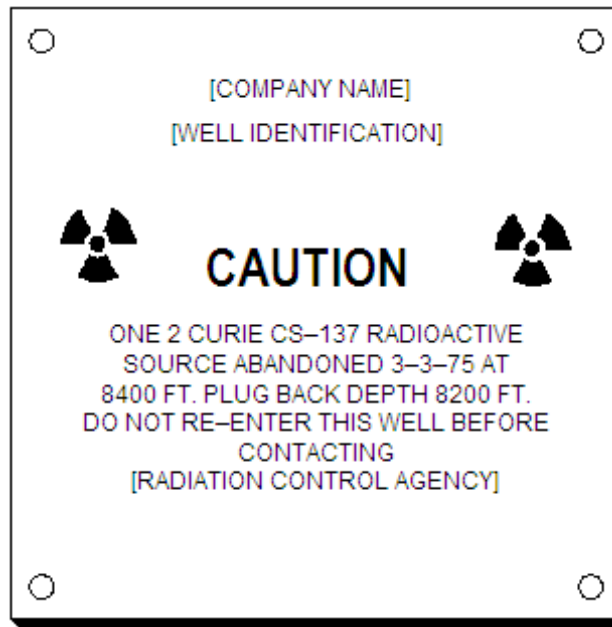
- A. Handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in 641—Chapter 40;
- B. Methods and occasions for conducting radiation surveys, including lock-out survey requirements;
- C. Methods for controlling access to industrial radiography areas;
- D. Methods and occasions for locking and securing sources or radiation;
- E. Personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off-scale;
- F. Methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable U.S. Department of Transportation requirements);
- G. Methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;
- H. Procedures for notifying proper personnel in the event of an accident;
- I. Specific posting requirements;
- J. Maintenance of records (Appendix C); and
- K. Inspection and maintenance of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines.

CHAPTER 45—APPENDIX E

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

- I. Fundamentals of radiation safety.
 - A. Characteristics of radiation.
 - B. Units of radiation dose and quantity of radioactivity.
 - C. Significance of radiation dose.
 - 1. Radiation protection standards.
 - 2. Biological effects of radiation dose.
 - D. Levels of radiation from sources of radiation.
 - E. Methods of minimizing radiation dose.
 - 1. Working time.
 - 2. Working distances.
 - 3. Shielding.
 - F. Radiation safety practices including prevention of contamination and methods of decontamination.
- II. Radiation detection instrumentation to be used.
 - A. Use of radiation survey instruments.
 - 1. Operation.
 - 2. Calibration.
 - 3. Limitations.
 - B. Survey techniques.
 - C. Use of personnel monitoring equipment.
- III. Equipment to be used.
 - A. Handling equipment.
 - B. Sources of radiation.
 - C. Storage and control of equipment.
 - D. Operation and control of equipment.
- IV. The requirements of pertinent federal and state regulations.
- V. The licensee's or registrant's written operating and emergency procedures.
- VI. The licensee's or registrant's record-keeping procedures.

CHAPTER 45—APPENDIX F

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES
CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word “CAUTION” should be approximately twice the letter size of the rest of the information, e.g., ½-inch and ¼-inch letter size, respectively.

These rules are intended to implement Iowa Code chapters 136B and 136C.

- [Filed 4/7/80, Notice 2/6/80—published 4/30/80, effective 7/1/80]
- [Filed 5/17/85, Notice 2/27/85—published 6/5/85, effective, see rule 41.7]
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[Filed ARC 8982B (Notice ARC 8762B, IAB 5/19/10), IAB 8/11/10, effective 9/15/10]
[Filed ARC 1639C (Notice ARC 1470C, IAB 5/28/14), IAB 10/1/14, effective 11/5/14]

CHAPTER 154
MEDICAL CANNABIDIOL ACT REGISTRATION CARD PROGRAM

641—154.1(85GA,SF2360) Definitions. For the purposes of these rules, the following definitions shall apply:

“*Cannabidiol*” means a nonpsychoactive cannabinoid found in the plant *Cannabis sativa L.* or *Cannabis indica* or any other preparation thereof that is essentially free from plant material, and has a tetrahydrocannabinol level of no more than 3 percent.

“*Date of expiration*” means one year from the date of issuance of the cannabidiol registration card by the department of transportation.

“*Date of issuance*” means the date of issuance of the cannabidiol registration card by the department of transportation.

“*Department*” means the Iowa department of public health.

“*Department of transportation*” means the Iowa department of transportation.

“*Intractable epilepsy*” means an epileptic seizure disorder for which standard medical treatment does not prevent or significantly ameliorate recurring, uncontrolled seizures or for which standard medical treatment results in harmful side effects.

“*Neurologist*” means an allopathic or osteopathic physician board-certified in neurology in good standing and licensed under Iowa Code chapter 148.

“*Patient*” means a person who is a permanent resident of the state of Iowa who suffers from intractable epilepsy and has received a recommendation from a neurologist for the medical use of cannabidiol pursuant to 2014 Iowa Acts, Senate File 2360.

“*Permanent resident*” means a natural person who physically resides in Iowa as the person’s principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver’s license,
2. A valid Iowa nonoperator’s identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,
7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child’s school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

“*Primary caregiver*” means a person, at least 18 years of age, who has been designated by a patient’s neurologist or a person having custody of a patient, as being necessary to take responsibility for managing the well-being of the patient with respect to the medical use of cannabidiol pursuant to the provisions of 2014 Iowa Acts, Senate File 2360.

“*State*” means a state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.2(85GA,SF2360) Neurologist recommendation—medical use of cannabidiol.

154.2(1) A neurologist who has examined and treated a patient suffering from intractable epilepsy may provide, but has no duty to provide, a written recommendation for the patient’s medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy if no other satisfactory treatment options exist for the patient and all of the following conditions apply:

- a. The patient is a permanent resident of Iowa.

b. A neurologist has treated the patient for intractable epilepsy for at least six months. For purposes of this treatment period, and notwithstanding 2014 Iowa Acts, Senate File 2360, section 3, subsection 4, treatment provided by a neurologist may include treatment by a neurologist licensed in another state and in good standing.

c. The neurologist has tried and documented alternative treatment options that have not alleviated the patient's symptoms.

d. The neurologist determines the risks of recommending the medical use of cannabidiol are reasonable in light of the potential benefit for the patient and has documented a discussion of the risks and benefits with the patient or the patient's parent or legal guardian.

e. The neurologist maintains a patient treatment plan. The neurologist shall have the sole, exclusive authority to recommend the use and amount of cannabidiol, if any, in the treatment plan, and shall recommend in the treatment plan only the oral or transdermal administration of cannabidiol.

f. The neurologist shall be available to provide follow-up care and treatment to the patient, including but not limited to patient examinations; however, this rule shall not restrict the authority of a neurologist to terminate the physician-patient relationship, provided that such termination is effectuated in accordance with rule 653—13.7(147,148,272C).

154.2(2) The neurologist is required to use the written recommendation section of the application form provided for this purpose on the department's Web site (www.idph.state.ia.us).

154.2(3) The neurologist, or authorized persons in the neurologist's office or clinic, is required to complete the written recommendation section of the application form and send the application to the department's address as provided on the application form.

154.2(4) A neurologist who provides a written recommendation pursuant to this chapter shall maintain a record-keeping system for all patients for whom the neurologist has recommended the medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy.

154.2(5) A neurologist who provides a written recommendation pursuant to this chapter is required to participate in any survey that will be conducted by the department on the implementation of the medical cannabidiol Act. Any such survey will adhere to the federal Health Insurance Portability and Accountability Act of 1996.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.3(85GA,SF2360) Cannabidiol registration card—application and issuance to patient.

154.3(1) The department may approve the issuance of a cannabidiol registration card by the department of transportation to a patient who:

- a.* Is at least 18 years of age.
- b.* Is a permanent resident of Iowa.
- c.* Requests the patient's neurologist to submit to the department, pursuant to rule 641—154.2(85GA,SF2360), a written recommendation signed by the neurologist that the patient may benefit from the medical use of cannabidiol.

d. Is listed as the patient on the application form submitted to the department, on a form created by the department in consultation with the department of transportation and available at the department's Web site (www.idph.state.ia.us) that contains all of the following:

(1) The patient's full legal name, Iowa residence address, mailing address (if different from the patient's residence address), telephone number, date of birth, and sex designation. The patient shall not provide as a mailing address an address for which a forwarding order is in place.

(2) A copy of the patient's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card, or
3. An alternative form of valid photo identification. A patient who possesses or is eligible for an Iowa driver's license or an Iowa nonoperator's identification card shall present such document as valid photo identification. A patient who is ineligible to obtain an Iowa driver's license or an Iowa nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the

patient's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(3) Full name, address, and telephone number of the patient's neurologist.

(4) Full legal name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) An attestation as to the truthfulness and accuracy of the information provided by the patient on the application.

154.3(2) Upon the completion, verification, and approval of the patient's application, the department shall notify the department of transportation that the patient may be issued a cannabidiol registration card.

154.3(3) A cannabidiol registration card issued to a patient by the department of transportation shall contain all of the following:

a. The patient's full legal name, Iowa residence address, date of birth, and sex designation, as shown on the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3." If the patient's name, Iowa residence address, date of birth, or sex designation has changed since the issuance of the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification, the patient shall first update the patient's Iowa driver's license or nonoperator's identification card to reflect the current information, according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321), or shall update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration.

c. A distinguishing registration number that is not the patient's social security number.

d. The patient's signature. The signature shall be without qualification and shall contain only the patient's usual signature without any other titles, characters, or symbols. The patient's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the patient's application for a cannabidiol registration card are true and correct. The patient's signature shall be captured electronically.

e. A color photograph of the patient.

f. A statement that the cannabidiol registration card is not valid for identification purposes.

154.3(4) A patient in possession of a valid cannabidiol registration card issued pursuant to this rule shall not possess a quantity of cannabidiol oil in excess of 32 ounces.

154.3(5) An authorization to use cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of 2014 Iowa Acts, Senate File 2360, or these rules for the issuance of a cannabidiol registration card.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.4(85GA,SF2360) Cannabidiol registration card—application and issuance to primary caregiver.

154.4(1) For a patient in a primary caregiver's care, the department may approve the issuance of a cannabidiol registration card by the department of transportation to a primary caregiver who:

a. Is at least 18 years of age.

b. Requests the patient's neurologist to submit to the department, pursuant to rule 641—154.2(85GA,SF2360), a written recommendation signed by the neurologist that the patient may benefit from the medical use of cannabidiol pursuant to 2014 Iowa Acts, Senate File 2360, section 4.

c. Is listed as a primary caregiver on the application form submitted to the department, on a form created by the department in consultation with the department of transportation and available at the department's Web site (www.idph.state.ia.us) that contains all of the following:

(1) The primary caregiver's full legal name, residence address, mailing address (if different from the primary caregiver's residence address), telephone number, date of birth, and sex designation. The primary caregiver shall not provide as a mailing address an address for which a forwarding order is in place.

(2) The patient's full legal name.

(3) A copy of the primary caregiver's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,
 2. A valid Iowa nonoperator's identification card,
 3. If the primary caregiver is not a resident of the state of Iowa, a valid state-issued driver's license or nonoperator's identification card issued by a state other than Iowa, or
 4. An alternative form of valid photo identification. A primary caregiver who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. A primary caregiver who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A primary caregiver who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.
- (4) Full name, address, and telephone number of the patient's neurologist.
- (5) An attestation as to the truthfulness and accuracy of the information provided by the primary caregiver on the application.

154.4(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall notify the department of transportation that the primary caregiver may be issued a cannabidiol registration card.

154.4(3) A cannabidiol registration card issued to a primary caregiver by the department of transportation shall contain all of the following:

- a. The primary caregiver's full legal name, current residence address, date of birth, and sex designation, as shown on the primary caregiver's state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.4(1) "c"(3)"4." If the primary caregiver's name, current residence address, date of birth, or sex designation has changed since issuance of the primary caregiver's Iowa-issued driver's license, nonoperator's identification card, or other form of valid photo identification, the primary caregiver shall first update the primary caregiver's Iowa-issued driver's license or nonoperator's identification card according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321) or update the alternative form of valid photo identification in accordance with the process of the issuing agency.
- b. The date of issuance and the date of expiration.
- c. A distinguishing registration number that is not the primary caregiver's social security number.
- d. The primary caregiver's signature. The signature shall be without qualification and shall contain only the primary caregiver's usual signature without any other titles, characters, or symbols. The primary caregiver's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the primary caregiver's application for a cannabidiol registration card are true and correct. The primary caregiver's signature shall be captured electronically.
- e. A color photograph of the primary caregiver.
- f. A statement that the cannabidiol registration card is not valid for identification purposes.
- g. A statement distinguishing the cannabidiol registration cardholder as a primary caregiver.
- h. The full name of each patient in the primary caregiver's care, as approved by the department in its notice to the department of transportation.

154.4(4) A primary caregiver in possession of a valid cannabidiol registration card issued pursuant to this rule shall not possess a quantity of cannabidiol oil in excess of 32 ounces per patient.

154.4(5) An authorization to use, or to act as a primary caregiver for a patient authorized to use, cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of 2014 Iowa Acts, Senate File 2360, or these rules for the issuance of a cannabidiol registration card.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.5(85GA,SF2360) Tamperproofing. The department of transportation shall issue a cannabidiol registration card by a method or process which prevents as nearly as possible the alteration, reproduction, or superimposition of a photograph on the cannabidiol registration card without ready detection.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.6(85GA,SF2360) Denial and cancellation. The department may deny an application for a cannabidiol registration card, or may cancel or direct the department of transportation to cancel a cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department or the department of transportation is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

3. The applicant violates or fails to satisfy any of the provisions of 2014 Iowa Acts, Senate File 2360, or these rules.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.7(85GA,SF2360) Appeal. If the department denies an application for or cancels a cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department’s address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.8(85GA,SF2360) Duplicate card.

154.8(1) Lost, stolen, or destroyed card. To replace a cannabidiol registration card that is lost, stolen, or destroyed, a cardholder shall present to the department of transportation the cardholder’s valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

154.8(2) Change in card information and voluntary replacement.

- a. To replace a cannabidiol registration card that is damaged, the cardholder shall surrender to the department of transportation the card to be replaced and present the cardholder’s valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

- b. A patient or primary caregiver to whom a cannabidiol registration card is issued shall notify the department of a change in current residence address, name, or sex designation listed on the card, within ten calendar days of the change. To replace a cannabidiol registration card to change the current residence address, name, or sex designation listed on the card, the cardholder shall surrender to the department of transportation the card to be replaced and present a valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4” that has been updated according to the procedures established by the state or agency of issuance to reflect the requested residence address, name, or sex designation.

- c. To replace a cannabidiol registration card held by a primary caregiver to change the patient or patients listed on the primary caregiver’s card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.4(85GA,SF2360). A cannabidiol registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) *Expiration date.* A duplicate cannabidiol registration card shall have the same expiration date as the cannabidiol registration card being replaced, changed, or amended.
[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.9(85GA,SF2360) *Renewal.* A cannabidiol registration card shall be valid for one year from the date of issuance unless canceled pursuant to rule 641—154.6(85GA,SF2360).

154.9(1) A cardholder seeking renewal of a cannabidiol registration card shall submit a renewal application to the department at least 60 days prior to the date of expiration.

a. A patient applying for renewal of a cannabidiol registration card shall submit a renewal application to the department on a form approved by the department.

b. A primary caregiver applying for a renewal of a cannabidiol registration card shall submit a renewal application to the department on a form approved by the department.

154.9(2) A cardholder who fails to renew the cannabidiol registration card may not lawfully possess cannabidiol pursuant to this chapter.
[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.10(85GA,SF2360) *Confidentiality.* The department shall maintain a confidential file of the names of each patient to or for whom the department approves the issuance of a cannabidiol registration card and the name of each primary caregiver to whom the department issues a cannabidiol registration card under 2014 Iowa Acts, Senate File 2360, section 5.

154.10(1) Personally identifiable information of patients and primary caregivers shall be maintained as confidential and is not accessible to the public. The department and the department of transportation shall release aggregate and statistical information regarding the medical cannabidiol act registration card program in a manner which prevents the identification of any patient or primary caregiver.

154.10(2) Personally identifiable information of patients and primary caregivers may be disclosed under the following limited circumstances:

a. To authorized employees or agents of the department and the department of transportation as necessary to perform the duties of the department and the department of transportation pursuant to this chapter.

b. To authorized employees of state or local law enforcement agencies located in Iowa, solely for the purpose of verifying that a person is lawfully in possession of a cannabidiol registration card issued pursuant to this chapter.

c. To a patient, primary caregiver, or neurologist, upon written authorization of the patient or primary caregiver.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

641—154.11(85GA,SF2360) *Agreement with department of transportation.* The department may enter into a chapter 28E agreement with the department of transportation to facilitate the issuance of cannabidiol registration cards. The agreement may include provisions which govern the issuance, denial, and cancellation of cannabidiol registration cards and the sharing of information between the department and the department of transportation.

[ARC 1640C, IAB 10/1/14, effective 1/30/15]

These rules are intended to implement 2014 Iowa Acts, Senate File 2360.

[Filed ARC 1640C (Notice ARC 1571C, IAB 8/6/14), IAB 10/1/14, effective 1/30/15]

CHAPTER 90
ADMINISTRATION OF THE BOILER AND PRESSURE VESSEL PROGRAM

[Prior to 1/14/98, see 347—Chs 41 to 49]

[Prior to 8/16/06, see 875—Chs 200, 202]

875—90.1(89) Purpose and scope. These rules institute administrative and operational procedures for implementation of Iowa Code chapter 89. An object shall not be considered “under pressure” and shall not be within the scope of Iowa Code chapter 89 when there is clear evidence that the manufacturer did not intend it to be operated at more than 3 psi and the object is operating at 3 psi or less.

[ARC 0416C, IAB 10/31/12, effective 12/5/12]

875—90.2(89,261,252J,272D) Definitions. To the extent they do not conflict with the definitions contained in Iowa Code chapter 89, the definitions in this rule shall be applicable to the rules contained in 875—Chapters 90 to 96.

“*Alteration*” means a change in a boiler or pressure vessel that substantially alters the original design requiring consideration of the effect of the change on the original design. It is not intended that the addition of nozzles smaller than an unreinforced opening size will be considered an alteration.

“*ANSI/ASME CSD-1*” means Control and Safety Devices for Automatically Fired Boilers.

“*ASME*” means the American Society of Mechanical Engineers.

“*Blowoff valve*” means all blowoff valves, drain valves, and pipe connections.

“*Boiler*” means a vessel in which water or other liquids are heated, steam or other vapors are generated, steam or other vapors are superheated, or any combination thereof, under pressure or vacuum by the direct application of heat. “Boiler” includes all temporary boilers.

“*Certificate of noncompliance*” means:

1. A certificate of noncompliance issued by the child support recovery unit, department of human services, pursuant to Iowa Code chapter 252J;
2. A certificate of noncompliance issued by the college student aid commission pursuant to Iowa Code chapter 261; or
3. A certificate of noncompliance issued by the centralized collection unit of the department of revenue pursuant to Iowa Code chapter 272D.

“*CFR*” means Code of Federal Regulations.

“*Construction or installation code*” means the applicable standard for construction or installation in effect at the time of installation.

“*Division*” means the division of labor services, unless another meaning is clear from the context.

“*Electric boilers*” means a power boiler, heating boiler, high or low temperature water boiler in which the source of heat is electricity.

“*External inspection*” means as complete an examination as can be reasonably made of the external surfaces and safety devices while the boiler or pressure vessel is in operation.

“*High temperature water boiler*” means a water boiler intended for operations at pressures in excess of 160 psig or temperatures in excess of 250 degrees F.

“*Hot water heating boiler*” means a boiler in which no steam is generated, from which hot water is circulated for heating purposes and then returned to the boiler, and which operates at a pressure not exceeding 160 psig or a temperature of 250 degrees F at the boiler outlet.

“*Hot water supply boiler*” means a boiler completely filled with water that furnishes hot water to be used externally to itself at pressures not exceeding 160 psig or at temperatures not exceeding 250 degrees F.

“*Institution of health and custodial care*” means any of the following:

1. A health care facility as defined by Iowa Code section 135C.1;
2. An assisted living program as defined by Iowa Code section 231C.2;
3. A boarding home as defined by Iowa Code section 1350.1;
4. A hospice that offers inpatient services in an institutional setting;
5. Any institution or facility in which persons are housed to receive medical, health, or other care or treatment; or

6. Any other institution or facility in which persons are housed to receive assistance with meeting personal needs or activities of daily living.

A facility or office that provides care and services only on an outpatient basis shall not be an “institution of health and custodial care.”

“*Internal inspection*” means as complete an examination as can be reasonably made of the internal and external surfaces of a boiler or pressure vessel while it is shut down and while manhole plates, handhole plates or other inspection opening closures are removed as required by the inspector.

“*ISO*” means International Standards Organization.

“*Labor commissioner*” means the labor commissioner or the commissioner’s designee.

“*Lap seam crack*” means a crack found in lap seams, extending parallel to the longitudinal joint and located either between or adjacent to rivet holes.

“*National Board*” means the National Board of Boiler and Pressure Vessel Inspectors, 1055 Crupper Avenue, Columbus, Ohio 43229, whose membership is composed of the chief inspectors of jurisdictions who are charged with the enforcement of the provisions of boiler codes.

“*National Board Inspection Code*” means the Manual for Boiler and Pressure Vessel Inspectors (ANSI/NB 23) published by the National Board. Copies of the code may be obtained from the National Board.

“*Object*” means a boiler or pressure vessel.

“*Power boiler*” means a boiler in which steam or other vapor is generated at a pressure of more than 15 pounds per square inch or a water boiler intended for operation at pressures in excess of 160 pounds per square inch or temperatures in excess of 250 degrees Fahrenheit.

“*Process steam generator*” means a vessel or system of vessels comprised of one or more drums and one or more heat exchange surfaces as used in waste heat or heat recovery type steam boilers.

“*Psig*” means pounds per square inch gage.

“*Reinstalled boiler or pressure vessel*” means an object removed from its original setting and reinstalled at the same location or at a new location.

“*Relief valve*” means an automatic pressure-relieving device actuated by a static pressure upstream of the valve that opens further with the increase in pressure over the opening pressure and that is used primarily for liquid service.

“*Repair*” means work necessary to return a boiler or pressure vessel to a safe operating condition.

“*Rupture disk device*” means a nonreclosing pressure-relief device actuated by inlet static pressure and designed to function by the bursting of a pressure-containing disk.

“*Safety appliance*” shall include, but not be limited to:

1. Rupture disk device;
2. Safety relief valve;
3. Safety valve;
4. Temperature limit control;
5. Pressure limit control;
6. Gas switch;
7. Air switch; or
8. Any major gas train control.

“*Safety relief valve*” means an automatic, pressure-actuated relieving device suitable for use as a safety or relief valve, depending on application.

“*Safety valve*” means an automatic, pressure-relieving device actuated by the static pressure upstream of the valve and characterized by full opening pop action. The safety valve is used for gas or vapor service.

“*Special inspection*” means an inspection which is not required by Iowa Code chapter 89.

“*Temperature and pressure relief valve*” means a valve set to relieve at a designated temperature and pressure.

“*Unfired steam boiler*” means a vessel or system of vessels intended for operation at a pressure in excess of 15 psig for the purpose of producing and controlling an output of thermal energy.

“Unfired steam pressure vessel” means a vessel or container used for the containment of steam pressure either internal or external in which the pressure is obtained from an external source.

“U.S. customary units” means feet, pounds, inches and degrees Fahrenheit.

“Water heater supply boiler” means a closed vessel in which water is heated by combustion of fuels, electricity or any other source and withdrawn for use external to the system at pressure not exceeding 160 psig and shall include all controls and devices necessary to prevent water temperatures from exceeding 210 degrees F.

[ARC 8283B, IAB 11/18/09, effective 1/1/10; ARC 9790B, IAB 10/5/11, effective 11/9/11; ARC 0319C, IAB 9/5/12, effective 10/10/12; ARC 0739C, IAB 5/15/13, effective 6/19/13]

875—90.3(89) Iowa identification numbers. All objects shall be identified by an Iowa identification number. State inspectors and special inspectors shall assign identification numbers as directed by the division to all jurisdictional objects that lack numbers. Identification numbers shall be attached in plain view to the object using one of the following methods:

1. A yellow sticker 2 inches by 3 inches affixed to the object and bearing the number.
2. A metal tag 1 inch by 2½ inches affixed to the object and bearing the number.
3. Numbers at least 5/16 of an inch high and stamped directly on the object.

875—90.4(89) National Board registration. Rescinded IAB 11/18/09, effective 1/1/10.

875—90.5(89) Preinspection owner or user preparation.

90.5(1) Preparation of objects. Each owner or user shall ensure that each object covered by Iowa Code chapter 89 is prepared for inspection pursuant to this rule.

90.5(2) Confined space and lockout, tagout procedures.

a. It is the responsibility of the owner or user to assess all objects for compliance with the confined space and lockout, tagout standards pursuant to 29 CFR 1910.146 and 1910.147. If an object is a non-permit-required confined space or a permit-required confined space as defined by 29 CFR 1910.146, the owner or user must comply with all applicable requirements of 29 CFR 1910.146 and 1910.147 in preparing the object for inspection.

b. It is the duty of the owner or user to inform any inspector of the owner's or user's confined space entry and lockout, tagout procedures and supply to the inspector all information necessary to assess whether the confined space is safe for entry. It is the right of an inspector to verify any of the information supplied.

c. If the requirements of 29 CFR 1910.146 and 1910.147 are not met, the inspector shall not enter the space. If there is a breach of the procedure or the procedure is inconsistent with 29 CFR 1910.146 or 1910.147, the inspection process shall cease until the space is reassessed and determined to be safe or the procedure is rewritten in a manner consistent with the standards. No inspector shall violate the owner's or user's confined space or lockout, tagout procedures in making an inspection.

d. The owner or user shall have all objects locked and tagged, as applicable, prior to the inspector's entry for inspection or testing.

e. For entry into a permit-required confined space, the owner or user shall provide the necessary equipment such as air monitors and a qualified attendant who has received all the information relevant to the entry.

90.5(3) Hydrostatic tests. The owner or user shall prepare for and apply a hydrostatic test, whenever necessary, on the date specified by the inspector, which date shall be not less than seven days after the date of notification.

90.5(4) Boilers. A boiler shall be prepared for internal inspection in the following manner:

- a. Fluid shall be drawn off and the boiler washed thoroughly.
- b. Manhole and handhole plates, washout plugs and inspection plugs in water columns shall be removed as required by the inspector. The furnace and combustion chambers shall be thoroughly cooled and cleaned.
- c. All grates of internally fired boilers shall be removed.

d. Brickwork shall be removed as required by the inspector in order to determine the condition of the boiler, header, furnace, supports or other parts.

e. Low-water fuel cutoff controls shall be opened or removed to allow for visual inspection.

90.5(5) Pressure vessels. The extent of inspection preparation for a pressure vessel will vary. If the inspection is to be external only, advance preparation is not required other than to afford reasonable access to the vessel. For combined internal and external inspections of small vessels of simple construction handling air, steam, nontoxic or nonexplosive gases or vapors, minor preparation is required, including affording reasonable means of access and removing manhole plates and inspection openings. In other cases, preparation shall include removing the internal fittings and appurtenances to permit satisfactory inspection of the interior of the vessel if required by the inspector.

90.5(6) Removal of covering or brickwork to permit inspection. If the object is jacketed so that the longitudinal seams of shells, drums, or domes cannot be seen, sufficient jacketing, setting wall, or other form of casing or housing shall be removed to permit reasonable inspection of the seams and so that the size of rivets, pitch of the rivets, and other data necessary to determine the safety of the object may be obtained, providing the information cannot be determined by other means. Brickwork shall be removed as required by the inspector in order to determine the condition of the boiler, header, furnace, supports or other parts.

90.5(7) Improper preparation for inspection. If an object has not been properly prepared for an internal inspection, or if the owner or user fails to comply with the requirements for hydrostatic tests as set forth in this chapter, the inspector may decline to make the inspection or test, and the inspection certificate shall be withheld until the owner or user complies with the requirements.

[ARC 9082B, IAB 9/22/10, effective 10/27/10]

875—90.6(89) Inspections.

90.6(1) General. All boilers and unfired steam pressure vessels covered by Iowa Code chapter 89 shall be inspected according to the requirements of the National Board Inspection Code (2011), which is hereby adopted by reference. A division inspector or special inspector must perform the inspections.

90.6(2) Schedule.

a. All required inspections must be performed according to the schedule set forth in Iowa Code section 89.3, unless an exception is set forth in this rule.

b. Except for inspections of unfired steam pressure vessels operating in excess of 15 pounds per square inch and low pressure steam boilers, each certificate inspection must be performed within a 60-day period prior to the expiration date of the operating certificate. Modification of this 60-day period will be permitted only upon written application showing just cause for waiver of the 60-day period.

c. Special inspections may be conducted at any time mutually agreed to by the division and the object's owner or user.

90.6(3) Inspections conducted by special inspectors. Special inspectors shall provide copies of the completed report to the insured and to the division within 30 days of the inspection. The reports shall list all adverse conditions and all requirements, if any. If the special inspector has not notified the division of the inspection results within 30 days of the expiration of an operating certificate, the division may conduct the inspection.

90.6(4) Type of inspection. The inspection shall be an internal inspection when required; otherwise, it shall be as complete an external inspection as possible. Conditions including, but not limited to, the following may also be the basis for an internal inspection:

- a. Visible metal or insulation discoloration due to excessive heat.
- b. Visible distortion of any part of the pressure vessel.
- c. Visible leakage from any pressure-containing boundary.
- d. Any operating records or verbal reports of a vessel being subjected to pressure above the nameplate rating or to a temperature above or below the nameplate design temperature.
- e. A suspected or known history of internal corrosion or erosion.
- f. Evidence or knowledge of a vessel having been subjected to external heat from a fire.
- g. A welded repair not documented as required.

h. Evidence of an accident, incident or malfunction that could affect or may have resulted from a problem with the object's integrity.

90.6(5) *Internal inspections for unfired steam pressure vessels operating at more than 15 pounds per square inch.* The commissioner may require an internal inspection of an unfired steam pressure vessel operating in excess of 15 psi when an inspector observes any deviation from these rules, Iowa Code chapter 89, the construction code, the installation code, or the National Board Inspection Code.

90.6(6) *Inspection of inaccessible parts.* When, in the opinion of the inspector, as a result of conditions disclosed at the time of inspection, it is advisable to remove the interior or exterior lining, covering, or brickwork to expose certain parts of the vessel not normally visible, the owner or user shall remove such material to permit proper inspection and thickness measurement of any part of the vessel. Nondestructive examination is acceptable.

90.6(7) *Imminent danger.* If the labor commissioner determines that continued operation of an object constitutes an imminent danger that could seriously injure or cause death to any person, notice to immediately cease operation of that object shall be posted by the labor commissioner. Upon such notice, the owner shall immediately begin the necessary steps to cease operation of the object. The object shall not be used until the necessary repairs have been completed and the object has passed inspection. Operation of an object in violation of this subrule may result in further legal action pursuant to Iowa Code sections 89.11 and 89.13.

90.6(8) *Internal inspections on a four-year cycle based on process safety management compliance.* The owner shall demonstrate compliance with the requirements set forth in Iowa Code section 89.3(5)“a”(4)(b) by annually submitting to the labor commissioner a notarized affidavit. The affidavit shall be in a format approved by the labor commissioner and shall be signed by the owner or an officer of the company.

90.6(9) *Internal inspection on a four-year cycle for utility objects.* An object that meets the criteria of this subrule shall be inspected internally at least once every four years and externally every year. If at any time the object or the owner no longer meets the criteria of this subrule, internal inspections shall be performed on a two-year cycle.

a. The object is owned and operated by an electric public utility subject to rate regulation under Iowa Code chapter 476.

b. The object and the owner meet all the requirements for a two-year internal inspection interval as set forth in Iowa Code section 89.3, subsection 4.

c. If the object is shut down for a period sufficient to allow safe entry, and more than two years have passed since the last internal inspection, the owner shall notify the labor commissioner of the outage and shall schedule an internal inspection.

d. If the labor commissioner determines that an earlier inspection is necessary, the owner shall prepare the object for inspection pursuant to rule 875—90.5(89).

[ARC 8283B, IAB 11/18/09, effective 1/1/10; ARC 0319C, IAB 9/5/12, effective 10/10/12; ARC 1189C, IAB 11/27/13, effective 1/1/14; ARC 1634C, IAB 10/1/14, effective 11/5/14]

875—90.7(89) Fees.

90.7(1) *Special inspector commission fee.* A \$55 fee shall be paid annually to the commissioner to obtain a special inspector commission pursuant to Iowa Code section 89.7.

90.7(2) *Certificate fee.* A \$40 fee shall be paid for each one-year certificate, an \$80 fee shall be paid for each two-year certificate, and a \$160 fee shall be paid for each four-year certificate.

90.7(3) *Fees for inspection.* An inspection fee for each object inspected by a division inspector shall be paid by the appropriate party as follows:

a. A \$55 fee for each water heater supply boiler.

b. A \$95 fee for each boiler, other than a water heater supply boiler, having a working pressure up to and including 450 pounds per square inch or generating between 20,000 and 100,000 pounds of steam per hour.

c. A \$215 fee for each boiler, other than a water heater supply boiler, having a working pressure in excess of 450 pounds per square inch and generating in excess of 100,000 pounds of steam per hour.

d. A \$55 fee for each pressure vessel, such as steam stills, tanks, jacket kettles, sterilizers and all other reservoirs having a working pressure of 15 pounds or more per square inch.

e. In addition to the applicable object's inspection fee, if the division cannot follow normal practice of scheduling inspections in a cost-effective manner due to a request by an owner or user for a customized schedule, travel expenses may be charged at the discretion of the division.

f. Upon receipt of a request for a state inspector to visit or inspect for a reason not required by Iowa Code chapter 89, the labor commissioner may negotiate an appropriate fee.

g. If a boiler or pressure vessel has to be reinspected, there shall be another inspection fee as specified above.

90.7(4) Fees for attempted inspections. A \$35 fee shall be charged for each attempt by a division inspector to conduct an inspection which is not completed through no fault of the division.

[ARC 7863B, IAB 6/17/09, effective 7/1/09; ARC 8081B, IAB 8/26/09, effective 9/30/09; ARC 0319C, IAB 9/5/12, effective 10/10/12; ARC 1422C, IAB 4/16/14, effective 5/21/14]

875—90.8(89) Certificate. A certificate to operate shall not be issued until the boiler or pressure vessel is in compliance with the applicable rules and all fees have been paid. The current certificate to operate or a copy of the current certificate to operate shall be conspicuously posted in the room where the object is installed.

875—90.9(89,252J,261) Special inspector commissions.

90.9(1) Application. A person applying for a commission shall complete, sign, and submit to the division with the required fee the form entitled "Application for Boiler and Pressure Vessel Special Inspector Commission" provided by the division. Additionally, the applicant shall submit a copy of the applicant's current National Board work card with each application.

90.9(2) Expiration. The commission is for no more than one year and ceases when the special inspector leaves employment with the insurance company, or when the commission is suspended or revoked by the labor commissioner. Each commission shall expire no later than June 30 of each year.

90.9(3) Changes. The special inspector shall notify the division at the time any of the information on the form or attachments changes.

90.9(4) Denials. The labor commissioner may refuse to issue or renew a special inspector's commission for failure to complete an application package, if the applicant or inspector does not hold a National Board commission, or for any reason listed in subrules 90.9(6) to 90.9(8).

90.9(5) Investigations. Investigations shall take place at the time and in the places the labor commissioner directs. The labor commissioner may investigate for any reasonable cause. The labor commissioner may conduct interviews and utilize other reasonable investigatory techniques. Investigations may be conducted without prior notice.

90.9(6) Reasons for probation. The labor commissioner may issue a notice of commission probation when an investigation reasonably reveals that the special inspector filed inaccurate reports.

90.9(7) Reasons for suspension. The labor commissioner may issue a notice of commission suspension when an investigation reasonably reveals the following:

- a. The special inspector failed to submit and report inspections on a timely basis;
- b. The special inspector abused the special inspector's authority;
- c. The special inspector misrepresented self as a state inspector or a state employee;
- d. The special inspector used commission authority for inappropriate personal gain;
- e. The special inspector failed to follow the division's rules for inspection of object repairs, alterations, construction, installation, or in-service inspection;
- f. The special inspector committed numerous violations as described in subrule 90.9(6);
- g. The special inspector used fraud or deception to obtain or retain, or to attempt to obtain or retain, a special inspector commission whether for one's self or another;
- h. The National Board revoked or suspended the special inspector's work card;
- i. The division received a certificate of noncompliance; or
- j. The special inspector failed to take appropriate disciplinary actions against a subordinate special inspector who has committed repeated acts or omissions listed in paragraphs "a" to "h" of this subrule.

90.9(8) Reasons for revocation. The labor commissioner may issue a notice of revocation of a special inspector's commission when an investigation reveals any of the following:

- a. The special inspector filed a misleading, false or fraudulent report;
- b. The special inspector failed to perform a required inspection;
- c. The special inspector failed to file a report or filed a report which was not in accordance with the provisions of applicable standards;
- d. The special inspector failed to notify the division in writing of any accident involving an object;
- e. The special inspector committed repeated violations as described in subrule 90.9(7);
- f. The special inspector used fraud or deception to obtain or retain, or to attempt to obtain or retain, a special inspector commission whether for one's self or another;
- g. The special inspector instructed, ordered, or otherwise encouraged a subordinate special inspector to perform the acts or omissions listed in paragraphs "a" to "f" of this subrule;
- h. The National Board revoked or suspended the special inspector's work card; or
- i. The division received a certificate of noncompliance.

90.9(9) Procedures. The following procedures shall apply except in the event of revocation or suspension due to receipt of a certificate of noncompliance. In instances involving receipt of a certificate of noncompliance, the applicable procedures of Iowa Code chapter 252J, 261, or 272D shall apply.

a. *Notice of actions.* The labor commissioner shall serve a notice on the special inspector by certified mail to an address listed on the commission application form or by other service as permitted by Iowa Code chapter 17A. A copy shall be sent to the insurance company employing the special inspector.

b. *Contested cases.* The special inspector shall have 20 days to file a written notice of contest with the labor commissioner. If the special inspector does not file a written contest within 20 days of receipt of the notice, the action stated in the notice shall automatically be effective.

c. *Hearing procedures.* The hearing procedures in 875—Chapter 1 shall govern.

d. *Emergency suspension.* Pursuant to Iowa Code section 17A.18A, if the labor commissioner finds that public health, safety or welfare imperatively requires emergency action because a special inspector failed to comply with applicable laws or rules, the special inspector's commission may be summarily suspended.

e. *Probation period.* A special inspector may be placed on probation for a period not to exceed one year for each incident causing probation.

f. *Suspension period.* A special inspector's commission may be suspended up to five years for each incident causing a suspension.

g. *Revocation period.* A special inspector's commission that has been revoked shall not be reinstated for five years.

h. *Concurrent actions.* Multiple actions may proceed at the same time against any special inspector.

i. *Revoked or suspended commissions.* Within five business days of final agency action revoking or suspending a special inspector commission, the special inspector shall forfeit the special inspector's commission card to the labor commissioner.

[ARC 8283B, IAB 11/18/09, effective 1/1/10]

875—90.10(89) Quality reviews, surveys and audits.

90.10(1) An entity that manufactures or repairs boilers, pressure vessels or related equipment may request quality reviews, surveys or audits from certifying organizations such as the ASME or the National Board. The division is authorized to conduct the quality reviews, surveys or audits. If the division performs the service, the manufacturer or repairer shall pay all applicable expenses.

90.10(2) Quality reviews, surveys and audits for certification to the National Board or ASME standards shall be conducted only by a person or organization designated by the labor commissioner. Any person or organization seeking this designation on behalf of the division shall provide documented evidence of training, examination, experience, and certification for the type of reviews, surveys and audits to be performed. The labor commissioner shall have final authority to determine qualifications and designations.

a. Assessing quality programs. The division recognizes the ASME and the National Board as qualified designees for conducting quality reviews, surveys and audits that lead to ASME or National Board program certification.

b. ISO 9000 assessments. The division recognizes the ASME and the National Board:

(1) To be acceptable ISO 9000 registrars of quality systems for boilers and pressure vessels and the related pressure-technology equipment industry;

(2) To certify auditors and lead auditors to the requirements of ISO 10011-2 1991(E), Annex A; and

(3) To conduct ISO 9000 assessments for the boiler, pressure vessel, and related pressure-technology equipment industry.

875—90.11(89) Notification of explosion. Owners and users of covered objects must report any object explosion by calling (515)281-3647 or (515)281-6533. If the explosion occurs during normal division operating hours, notification shall occur before close of business on that day. If the explosion occurs when the division office is closed, the notification shall occur no later than close of business on the next division business day. Division hours are 8 a.m. to 4:30 p.m., Monday through Friday, except state holidays.

875—90.12(89) Publications available for review. Pursuant to Iowa Code section 89.5, subsection 3, the standards, codes, and publications adopted by reference in these rules are available for review in the office of the Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa.

875—90.13(89) Notice prior to installation. Written notice of intent to install objects subject to the jurisdiction of Iowa Code chapter 89 shall be provided to the labor commissioner at least ten days before installation. Written notice shall be accomplished by completing and submitting to the labor commissioner either:

1. The form designated by the labor commissioner, or
2. The National Board's Boiler Installation Report, I-1.

875—90.14(89) Temporary boilers. A certificate to operate a temporary boiler shall expire one year from the date of issuance or when the temporary boiler is disconnected. Inspections on temporary boilers that remain in one location longer than one year shall be performed according to the inspection schedule of Iowa Code section 89.3. A temporary boiler that is installed at a different location less than a year since the prior internal inspection of the boiler shall be subjected to a hydrostatic test pursuant to the National Board Inspection Code or to an internal inspection, at the discretion of the inspector.

875—90.15(89) Conversion of a power boiler to a low-pressure boiler. The following requirements apply to the conversion of a power boiler to a low-pressure boiler. The owner shall comply with the requirements of subrule 90.15(1) for each conversion. In addition, the owner shall comply with the requirements of subrule 90.15(2) if the converted object will be located outside of a place of public assembly or with the requirements of subrule 90.15(3) if the converted object will be located in a place of public assembly.

90.15(1) General requirements.

a. The owner shall provide to the labor commissioner written notice of intent to convert a power boiler to a low-pressure boiler prior to conversion. The required form for a notice of conversion is available at http://www.iowaworkforce.org/labor/boiler_inspection_.htm. At a minimum the notice shall contain the following:

- (1) Address, uses, and owner of the building where the boiler is located.
- (2) The Iowa identification number assigned to the boiler.
- (3) Name and contact information for the person completing the notice.
- (4) Name and contact information for the contractor or other person planning to perform the conversion.

b. Pressure controls shall not exceed 14 pounds per square inch.

- c. All boiler controls shall comply with ASME CSD-1.
- d. Safety valves and safety relief valves shall be manufactured in accordance with a national or international standard.
- e. One or more spring-pop safety valves meeting the following requirements shall be installed on each steam boiler:
 - (1) The valve shall be adjusted and sealed to discharge at a pressure not to exceed 15 psig.
 - (2) The valve capacity shall be certified by the National Board.
- f. The converted boiler shall be subject to post-conversion external inspection to ensure that the requirements of this rule are met.

90.15(2) *Boilers located outside places of public assembly.* A power boiler that was converted to a low-pressure boiler and that is located outside of a place of public assembly shall not be converted back to a power boiler unless the following requirements are met:

- a. The owner shall notify the labor commissioner at least ten days prior to converting the boiler.
- b. The owner shall comply with the editions of ASME Section I and CSD-1 in effect at the time of the second conversion.
- c. The owner shall comply with the version of 875—Chapter 92 in effect at the time of the second conversion.

90.15(3) *Boilers located in places of public assembly.* A power boiler converted to a low-pressure boiler that is located in a place of public assembly shall comply with 875—Chapter 94.

[ARC 9232B, IAB 11/17/10, effective 12/22/10]

These rules are intended to implement Iowa Code chapters 17A, 89, 252J, 261, and 272D.

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[◇] Two or more ARCs

¹ Date corrected IAC Supp. 3/26/08